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* The form pages are numbered differently (AA, BB, CC, etc.) for automation purposes. Therefore, they are not counted in the general pagination (1,2,3 etc.).

FOREWORD

The PHS 398 instructions contain information for preparing applications for:

- Public Health Service (PHS) research grants,
- Research Career Awards, and
- Institutional National Research Service Awards (training grants).

The PHS 398 is required for all new, revised, competing continuation, and supplemental research grant, research training grant, and cooperative agreement applications.

These instructions are formatted so specific instructions for completing the application appear first, followed by sample form pages and general information on submitting the application. The third section contains definitions, assurances, and other relevant information. The fourth and fifth sections contain additional information pertinent to research career awards and institutional training grants.

Note that this packet contains sample application forms only. Blank form pages are available separately from the applicant's office of sponsored research and on the NIH Web site. Investigators are encouraged to retain these instructions for future submissions. The NIH does not distribute any software for computer generation of the application. However, the forms, in Adobe Acrobat, can be downloaded from the NIH Web site at http://www.nih.gov/grants/forms.htm. Future developments in electronic transfer of applications will be published periodically in the *NIH Guide for Grants and Contracts* and/or posted periodically on the NIH Web site at http://www.nih.gov/grants/era/era.htm.

These instructions and application forms (4/98) supersede all previous editions. Applicants should give careful attention to the instructions, because an application that fails to meet the PHS requirements may be returned. A properly prepared application will facilitate the administrative processing and peer review that must occur before an award can be made.

While these instructions are generally applicable, many grant programs have additional, specific instructions. Applicants should contact an official of the PHS awarding component (Institute, Center, or other unit) to obtain the most current information and instructions (see page 23).

GrantsInfo, DEOIR, OER, National Institutes of Health

The Division of Extramural Outreach and Information Resources (DEOIR) is the central source for general information about NIH extramural research and research training programs, funding mechanisms, the peer review system, and application procedures. The NIH grants Web site is at **http://www.nih.gov/grants/oer.htm**. The e-mail address is: GrantsInfo@nih.gov. The phone number is (301) 435-0714. A listing of other NIH Web sites can be found on page 40.

Grants Policy Statement

The *PHS Grants Policy Statement* is a compilation of the salient features of policies and various policy issues regarding the administration of PHS grant awards. This publication is generally available in institutional offices of sponsored research. If not available, a copy may be obtained from the NIH Web site or from GrantsInfo.

NIH is in the process of creating the *NIH Grants Policy Statement* which will replace the *PHS Grants Policy Statement* in its entirety. An *NIH Guide* announcement will be issued when the document is available. Copies will be automatically mailed to current recipients and an electronic version will be posted on the NIH grants Web site.

NIH Guide for Grants and Contracts

The *NIH Guide for Grants and Contracts*, a weekly publication, contains all NIH requests for applications (RFAs) and program announcements (PAs), RFAs and PAs from other PHS agencies, and vital information about NIH and PHS policies and procedures. The *NIH Guide* is available on the NIH Web site at http://www.nih.gov/grants/guide or via LISTSERV e-mail. For instructions to subscribe, visit http://www.nih.gov/grants/guide/listserv.htm.

The PHS estimates that it will take approximately 40 hours to complete this application for a regular research project grant. This estimate does not include time for development of the scientific plan. Items such as human subjects and vertebrate animals are cleared and accounted for

separately, and are therefore also not part of the time estimate. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. If you have comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, send comments to: NIH, Project Clearance Office, 6701 Rockledge Drive MSC 7730, Bethesda, MD 20892-7730, ATTN: PRA (0925-0001).
Do not send applications to this address.

Form Approved Through 2/28/01
OMB No. 0925-0001

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Grant Application (PHS 398)

SECTION I.
PREPARING YOUR APPLICATION

A. Introduction

These instructions pertain to applications for traditional, unsolicited, and investigator-initiated research project grants. Use the additional instructions and sample pages included in sections IV and V of this document when applying for Research Career Awards or Institutional National Research Service Awards.

When applying for other specialized grants or cooperative agreements, request additional instructions from the appropriate PHS awarding component. Phone numbers for contacting these awarding components are listed on page 23. For further assistance, contact GrantsInfo, National Institutes of Health (NIH), e-mail: GrantsInfo@nih.gov, (301) 435-0714.

Many Requests for Applications (RFAs) incorporate On-Time (Just-in-Time) procedures. Thus, it is important for applicants planning to respond to RFAs to review those announcements carefully for special On-Time instructions.

1. Requests for Applications/ Program Announcements

When responding to a specific request for applications (RFA) or program announcement (PA) published in the *NIH Guide for Grants and Contracts*, the *Federal Register*, or other public media, contact the issuing PHS component for additional instructions. Each RFA and PA contains contact information under INQUIRIES.

2. Authorization

The PHS requests the information described in these instructions pursuant to its statutory authorities for awarding grants, contained in Sections 301 (a) and 487 of the PHS Act, as amended (42 USC 241a and 42 USC 288). Therefore, such information must be submitted if an application is to receive due consideration for an award. Lack of sufficient information may hinder the PHS's ability to review an application and to monitor the grantee's performance.

B. General Instructions

Read and follow the instructions carefully to avoid delays and misunderstandings.

In preparing the application, use English and avoid jargon. For terms not universally known, spell out the term the first time it is used, with the appropriate abbreviation in parentheses; the abbreviation may be used thereafter.

Prepare the application single-sided and single-spaced, staying within the margin limitations indicated on the form and continuation pages. The print must be clear and legible. Use standard size, black letters (see page 6) that can be clearly copied. Do **not** use photoreduction. Prepare all graphs, diagrams, tables, and charts in black ink. The application must contain only material that can be photocopied; glossy photographs or other materials that cannot be photocopied must be submitted in five collated sets as appendices (see page 19).

You may substitute computer-generated facsimiles, but they must maintain the exact wording and format of the government-printed forms, including all captions and spacing. Deviations may be grounds for the PHS to reject the entire application.

Observe the page number limitations or the application will be returned without review. A summary of these limitations is given in the following chart:

PAGE LIMITATIONS AND CONTENT REQUIREMENTS

Section	Page Limit	Content
Introduction		
Revised applications	3	See instructions on page 14
Supplemental applications	1	See instructions on page 14
Research Plan		
Sections a-d	25 (some exclusion for competing continuation applications)	Text plus all figures, charts, tables, and diagrams
Biographical Sketches	2 each	Not more than two pages for **each** key person
Literature Cited	—	Complete citations, including titles and **all** authors
Appendix	—	No more than 10 publications, including accepted or submitted manuscripts
		Photographs (include a copy in the Research Plan)
		Questionnaires
		Other materials that do not photocopy well

Only in cases involving interdependent multiple subprojects (e.g., Program Projects, Multi-Center Clinical Trials) will the PHS determine that applications exceeding the page number limitations are acceptable. However, specific page number limits may apply to each subproject. For information pertaining to page number limits for such projects, contact the awarding component to which the application may be assigned (see page 23). The page number limitations may also be different for other specialized grant applications. For information regarding page number limitations, request and follow the additional instructions for those applications. Any additional questions should be directed to the Division of Receipt and Referral, Center for Scientific Review, (301) 435-0715.

Observe type size specifications throughout the application, or the application will be returned without review. Adherence to type size and line spacing requirements is necessary for several reasons. No applicants should have the advantage, by using small type, of providing more text in their applications. Small type may also make it difficult for reviewers to read the application.

The application must be clear, readily legible, and conform to the following three requirements: 1) The height of the letters must not be smaller than 10 point; 2) Type density must be no more than 15 characters per inch (cpi). For proportional spacing, the average for any representative section of text must not exceed 15 cpi; 3) No more than 6 lines of type must be within a vertical inch. Type requirements should be checked using a standard device for measuring type size, rather than relying on the font selected for a particular word processing/printer combination. Figures, charts, tables, figure legends, and footnotes may be smaller in size but must be readily legible. The type size used throughout the application must conform to all three requirements.

The Division of Receipt and Referral has the responsibility and authority to make the final determination of legibility. Further inquiries should be directed to the Division of Receipt and Referral, Center for Scientific Review, (301) 435-0715.

C. Specific Instructions

1. Face Page (Follow the character length restrictions noted on the sample Face Page-AA.)

Item 1. Title of Project. Do not exceed 56 characters, including the spaces between words and punctuation. Choose a title that is specifically descriptive, rather than general. A **new** application must have a different title from any other PHS project with the same principal investigator/program director. A **competing continuation** or **revised** application should ordinarily have the same title as the previous grant or application. If the specific aims of the project have significantly changed, choose a new title. A **supplemental** application **must** have the same title as the currently funded grant.

Item 2. Response to Specific Request for Applications (RFA) or Program Announcement (PA). If the application is submitted in response to an

RFA or a PA, check "Yes" and identify the number of the RFA or the number and title of the PA. For RFAs only, attach the RFA label or a facsimile to the bottom of the face page of the original application. The RFA label is under the general mailing label, which is after the checklist and personal data pages. In addition, identify certain grant applications such as for the Research Career Award, Academic Research Enhancement Award (AREA), Institutional National Research Service Award, and AIDS research.

Item 3. Principal Investigator/Program Director.

New Investigator. Check the "New Investigator" box **only** if the principal investigator has not previously served as such on any PHS-supported research project other than a small grant (R03), an Academic Research Enhancement Award (R15), an exploratory/developmental grant (R21), or certain research career awards directed principally to physicians, dentists, or veterinarians at the beginning of their research career (K01, K08, K22, and K23). Current or past recipients of Independent Scientist and other nonmentored career awards (K02 and K04) are not considered new investigators.

Item 3a. Name of Principal Investigator/Program Director. Name the **one** person responsible to the applicant organization for the scientific and technical direction of the project. A supplemental application **must** have the same principal investigator/program director as the currently funded grant. The concept of coprincipal investigators is not formally recognized. PHS staff conduct official business only with principal investigators and institutional officials.

Item 3b. Degree(s). Indicate up to three academic and professional degrees or other credentials, such as licenses, e.g., R.N.

Item 3c. Social Security Number. Do not complete this item. The Social Security Number (SSN) of the principal investigator should be provided at the top of the Personal Data Page (Form Page KK) **only**. The SSN should **not** be listed elsewhere in the application, for example, on the top of each application page.

Item 3d. Position Title. Provide the academic or professional title of the principal investigator/ program director. If more than one title, indicate the one most relevant to the proposed project, such as Professor of Biochemistry, Chief of Surgical Service, or Group Leader.

Item 3e. Mailing Address. Provide complete information (including room number, building, and street address) necessary for postal delivery. All written communications with the principal investigator will use this address. For electronic mail, enter the appropriate e-mail address.

Item 3f. Department, Service, Laboratory, or Equivalent. Indicate your organizational affiliation, such as department of medicine, materials research laboratory, or social sciences institute.

Item 3g. Major Subdivision. Indicate your school, college, or other major subdivision, such as medical, dental, engineering, graduate, nursing, or public health. If there is no such subdivision, enter "None."

Item 3h. Telephone and Fax Numbers. Provide a daytime telephone number and, if available, a fax number.

Item 4. Human Subjects. If activities involving human subjects are **not** planned **at any time** during the proposed project period, check "No." The remaining parts of Item 4 are then not applicable.

If activities involving human subjects, whether or not exempt from Federal regulations for the protection of human subjects, are planned **at any time** during the proposed project period, either at the applicant organization or at any other performance site or collaborating institution, check "'Yes." If the activities are designated to be exempt from the regulations, insert the exemption number(s) corresponding to one or more of the six exemption categories (see pages 27-28). The remaining parts of Item 4 are then not applicable. Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research may result in delays in the review of an application. The PHS will make a final determination as to whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the Research Plan. In doubtful cases, consult with the Office for Protection from Research Risks (OPRR), National Institutes of Health, Rockville, MD 20892, (301) 496-7041.

If the planned activities involving human subjects are not exempt, complete the remaining parts of Item 4. If the applicant organization has an approved Multiple Project Assurance of Compliance on file with the OPRR that covers the specific activity, insert the Assurance number and the latest date of approval by the Institutional Review Board

(IRB) of the proposed activities. This date must be no earlier than one year before the receipt date for which the application is submitted. Check the type of IRB review in the appropriate box. An IRB of an institution with a Multiple Project Assurance may review an application through an expedited review procedure only if it complies with Section 46.110 of the human subject regulations 45 CFR 46.

If the IRB review is unavoidably delayed beyond the submission of the application, enter "Pending" in the box requesting IRB approval date. A follow-up certification of IRB approval from an official signing for the applicant organization must then be sent to and received by the scientific review administrator of the scientific review group (SRG). The certification must be received within 60 days after the receipt date for which the application is submitted. This follow-up certification must include: the PHS application number, title of the project, name of the principal investigator/program director, institution, Multiple Project Assurance number, date of IRB approval, and appropriate signatures.

Any modifications in the Research Plan section of the application, required by the IRB, must be submitted with the follow-up certification. It is the responsibility of the principal investigator/program director and the applicant organization to submit the follow-up certification. The PHS does not guarantee that it will remind the applicant organization or the principal investigator/program director to provide this missing information. If certification of IRB approval is not received within 60 days after the application receipt date, the application will be considered incomplete and deferred to the next review cycle.

The name and address of the scientific review administrator of the scientific review group will be sent to the principal investigator/program director and applicant organization as soon as possible after the receipt date, usually within 6 weeks. To avoid delays in review, send the follow-up information directly to the scientific review administrator.

If the applicant organization does not have an approved Assurance of Compliance on file with OPRR, insert "None" in Item 4b. In this case, the applicant organization, by the signature on the face page, is declaring that it will comply with 45 CFR 46 within 30 days of a specific request from OPRR.

When a year will have elapsed between the initial IRB review date certified by a Multiple Project Assurance and the anticipated award date, awarding unit staff shall require re-review and certification prior to award.

Item 5. Vertebrate Animals. If activities involving vertebrate animals are **not** planned **at any time** during the proposed project period, check "No." The remaining parts of Item 5 are then not applicable.

If activities involving vertebrate animals are planned **at any time** during the proposed project period, either at the applicant organization or at any other performance site or collaborating institution, check "Yes." If the applicant organization has an approved Animal Welfare Assurance on file with the Office for Protection from Research Risks (OPRR), insert the Assurance number at Item 5b. In addition, provide the date of approval by the Institutional Animal Care and Use Committee (IACUC).

If the IACUC review is unavoidably delayed beyond the submission of the application, enter "Pending" in the box requesting IACUC approval date. A follow-up verification of IACUC approval from an official signing for the applicant organization must then be sent to and received by the scientific review administrator of the SRG. The verification must be received within 60 days after the receipt date for which the application is submitted. This follow-up verification must include: the PHS application number, title of project, name of principal investigator/program director, institution, Animal Welfare Assurance number, date of IACUC approval, and appropriate signatures.

Any modifications of the Research Plan section of the application, required by the IACUC, must be submitted with the follow-up verification. It is the responsibility of the principal investigator/program director and the applicant organization to submit the follow-up verification. The PHS does not guarantee that it will remind the applicant organization or the principal investigator/program director to provide this missing information. If verification of IACUC approval is not received within 60 days after the application receipt date, the application will be considered incomplete and deferred to the next review cycle.

The name and address of the scientific review administrator of the scientific review group will be sent to the principal investigator/program director and applicant organization as soon as possible after the receipt date, usually within 6 weeks. To avoid delays in review, send the follow-up information directly to the scientific review administrator.

If the applicant organization does not have an approved Animal Welfare Assurance on file with OPRR, insert "None" in Item 5b. In this case, the applicant organization, by the signature on the face page, is declaring that it will comply with PHS policy regarding the care and use of animals by establishing an IACUC and submitting an Animal Welfare Assurance and verification of IACUC approval when requested to do so by OPRR.

Item 6. Dates of Proposed Period of Support. Request no more than 5 years of support. To select an appropriate beginning date for a **new** application, consult the review and award schedule (see page 21). For a **competing continuation** application, choose a beginning date immediately following the termination date of the current period of support. Submit a **supplemental** application only for a period within the current period of support. Make the ending date of the supplement's first budget period coincide with the ending date of the budget period that is to be supplemented, regardless of the supplement's beginning date. If requesting supplemental funds for the future years of a currently funded grant, make the future years' budget periods coincide with those of the currently funded grant.

PHS awarding components may not always be able to honor the requested start date. No commitments or obligations should be made until confirmation of the actual start date by the awarding component.

All amounts requested in Items 7 and 8 and on the budget pages must be in U.S. dollars.

Item 7. Costs Requested for Initial Budget Period.

Item 7a. Direct Costs Requested for Initial Budget Period. Enter the direct costs from Form Page 4 (DD). If greater than $500,000, see instructions on page 11.

Item 7b. Total Costs Requested for Initial Budget Period. Enter the sum of the total direct costs from Form Page 4 and the Facilities and Administration costs for the initial budget period, as calculated on the Checklist (II).

Item 8. Costs Requested for Proposed Period of Support.

Item 8a. Direct Costs Requested for Proposed Period of Support. Enter the direct costs from Form Page 5 (EE).

Item 8b. Total Costs Requested for Proposed Period of Support. Enter the sum of the total direct costs from Form Page 5 and the Facilities and Administration costs for the proposed period of support, as calculated on the Checklist (II).

Item 9. Applicant Organization. Name the one organization that will be legally and financially responsible for the conduct of activities supported by the award.

Item 10. Type of Organization. Check the appropriate box. See page 24 for definitions.

Item 11. Organizational Component Code. Enter the appropriate code:

Academic Institutions

Code	Identification
01	School of Medicine
03	School of Dentistry
05	School of Osteopathy
07	School of Pharmacy
09	School of Nursing
11	School of Veterinary Medicine
13	School of Public Health
14	School of Optometry
15	School of Allied Health
16	College of Podiatric Medicine
20	Other Academic

Nonacademic Institutions

Code	Identification
30	Hospital
52	Health Department
60	Research Organization
70	Other Nonacademic

Item 12. Entity Identification Number, DUNS Number, Congressional District. Enter the number assigned to the applicant organization by the Department of Health and Human Services for payment and accounting purposes. If a number has not yet been assigned, enter the organization's Internal Revenue Service employer identification number (nine digits). If a Dun & Bradstreet (DUNS) number is available, it should also be entered. The DUNS number is a nine digit identification code assigned by Dun & Bradstreet. Also, enter the number of the Congressional District.

Item 13. Administrative Official to be Notified If Award Is Made. Name the applicant organization administrative official to be notified if an award is made. Provide a complete address for postal delivery and the telephone, fax, and e-mail address.

In the context of reinvention and electronic research administration, NIH has begun the transition from paper to electronic exchange of information. NIH recommends that grant recipients establish a generic and stable e-mail address specifically for this purpose. Provide, in the last line of Item 13, the e-mail address established to receive electronic Notices of Grant Award (NGA). In the event the

space provided is inadequate, enter the e-mail address on the Table of Contents page (Form Page CC).

The Notice of Grant Award will be sent to this central e-mail address. The institution is responsible for distributing the NGA, along with any special terms and conditions, to the principal investigator and other appropriate officials within the recipient organization.

Item 14. Official Signing for Applicant Organization. Name an individual authorized to act for the applicant organization and to assume the obligations imposed by the Federal laws, requirements, and conditions for a grant or grant application, including the applicable Federal regulations. For electronic mail, enter the appropriate e-mail address.

Item 15. Principal Investigator/Program Director Assurance. An original signature, in ink, is required. "Per" signatures are not acceptable. Date of signature must be included.

Item 16. Applicant Organization Certification and Acceptance. An original signature, in ink, is required. "Per" signatures are not acceptable. Date of signature must be included. In signing the application face page, the duly authorized representative of the applicant organization certifies that the applicant organization will comply with all applicable assurances and certifications referenced in the application. The applicant organization is responsible for verifying the accuracy, validity, and conformity with the most current institutional guidelines of all the administrative, fiscal, and scientific information in the application, including the Facilities and Administration (Indirect Cost) rate. Deliberate withholding, falsification, or misrepresentation of information could result in administrative actions, such as withdrawal of an application, suspension and/or termination of an award, debarment of individuals, as well as possible criminal penalties. The signer further certifies that the applicant organization will be accountable both for the appropriate use of any funds awarded and for the performance of the grant supported project or activities resulting from this application. The grantee institution may be liable for the reimbursement of funds associated with any inappropriate or fraudulent conduct of the project activity.

Assurances/Certifications

Each application to the PHS requires that the following assurances and certifications be verified by the signature of the Official Signing for Applicant Organization on the Face Page of the application. Definitions are provided in the Grants Policy Statement and in Section III of these instructions.

Human Subjects
Vertebrate Animals
Debarment and Suspension
Drug-Free Workplace
Lobbying
Delinquent Federal Debt
Research Misconduct
Civil Rights
Handicapped Individuals
Sex Discrimination
Age Discrimination
Financial Conflict of Interest

Notice of Proprietary Information

When the application contains information that constitutes trade secrets; or information that is commercial or financial; or information that is confidential or privileged, the information must be identified by asterisks (*) and page number in the Research Plan. The information is furnished to the Government in confidence with the understanding that it shall be used or disclosed only for evaluation of this application; provided that, if a grant is awarded as a result of, or in connection with, the submission of this application, the Government shall have the right to use or disclose the information to the extent authorized by law. This restriction does not limit the Government's right to use the information if it is obtained without restriction from another source.

2. Description, Performance Sites, and Key Personnel (Form Page 2-BB)

Description

Note the instructions on the form page. If the application is funded, the project description will be entered into an NIH database (CRISP) and will become public information. **Therefore, do not include proprietary or confidential information in the description.**

Performance Site(s)

Indicate where the work described in the Research Plan will be conducted. If there is more than one performance site, list all the sites, including V.A. facilities and foreign sites, and provide an explanation on the Resources page (HH) of the application. One of the sites indicated must be the applicant organization or be identified as off-site in accordance with the conditions of the applicant organization's

negotiated Facilities and Administration (F&A) agreement. This information must agree with the F&A information on the Checklist page of the application. State if a consortium/contractual arrangement is involved with one or more collaborating organizations for the conduct of a portion of the work described in the Research Plan.

Key Personnel. Key personnel are defined as, and should be limited to, individuals who contribute in a substantive way to the scientific development or execution of the project, whether or not salaries are requested.

Typically, these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level should be included if their involvement meets the definition of key personnel. Consultants should be included only when their level of involvement meets the definition. Individuals providing technical services are not considered key personnel. For each individual provide: name, organization, and role on the project. Under role on the project, indicate how the individual will function with regard to the proposed project, for example, principal investigator, graduate research assistant, etc. Use additional pages as necessary.

3. Research Grant Table of Contents (Form Page 3-CC)

Provide the page number for each category listed on the Table of Contents. Number pages consecutively at the bottom of each page throughout the application. Do not include unnumbered pages and do not use suffixes, such as 5a, 5b.

4. Detailed Budget for Initial Budget Period (Form Page 4-DD)

Note: An NIH applicant planning to submit an investigator-initiated new (type 1), competing continuation (type 2), competing supplement or any amended/revised version of the preceding grant application types requesting $500,000 or more in direct costs for any year is advised that he or she must contact Institute or Center program staff before submitting the application. A cover letter must be sent with the application identifying the staff member and NIH Institute or Center who agreed to accept assignment of the application. If unsure which Institute or Center to contact, call the Division of Receipt and Referral, NIH at (301) 435-0715. This policy does not apply to applications submitted in response to RFAs. However, an application submitted in response to an RFA must be responsive to any budgetary limits specified in the RFA.

Each item listed in the budget must be clearly justified on Form Page 5. All amounts must be in U.S. dollars. List only the direct costs requested in this application. Do not include any items that are treated by the applicant organization as Facilities and Administration (F&A) costs according to a Federal rate negotiation agreement, except for those F&A costs included in consortium/contractual costs.

For a **supplemental** application, show only those items for which additional funds are requested. If the initial budget period of the supplemental application is less than 12 months, prorate the personnel costs and other appropriate items of the detailed budget.

Foreign Justification

For projects with a substantial foreign component, explain and justify on Form Page 5. For a definition of a substantial foreign component, see page 25.

Personnel

Name

Starting with the principal investigator, list the names of all applicant organization employees who are involved on the project during the initial budget period, regardless of whether a salary is requested. Include all collaborating investigators, individuals in training, and support staff. The PHS does not recognize the use of a co-principal investigator title.

Role on Project

Identify the role of each individual listed on the project. Describe their specific functions under Justification on Form Page 5.

Type of Appointment/Months

List the number of months per year reflected in an individuals contractual appointment to the applicant organization. **PHS staff assume that appointments at the applicant organization are full time for each individual.** If an appointment is less than full time, e.g., 50 percent time, identify with an asterisk (*) and provide a full explanation under Justification on Form Page 5. Individuals may have split appointments, for example for an academic period and a summer period. For each appointment, identify and enter the number of

months on separate lines. In cases where no contractual appointment exists with the applicant organization and salary is requested, enter the number of months for that period.

Percent of Effort on Project

For each individual at the applicant organization, list the percent of each appointment to be spent on this project.

Institutional Base Salary

An applicant organization may choose to leave this column blank. However, PHS staff will require this information prior to award. See definition on page 25 for additional information.

Dollar Amount Requested

Salary Requested

Enter the dollar amounts for each position for which funds are requested. The salary requested is calculated by multiplying the individual's institutional base salary by the percent of effort on this project. Explain under Justification on Form Page 5 if a lesser amount is requested, e.g., endowed position or institutional sources.

Some PHS grant recipients are currently subject to a legislatively imposed salary limitation. Any adjustment for salary limits will be made at the time of award. For guidance on current salary limitations, see the *NIH Guide for Grants and Contracts* on the NIH grants Web site or contact your office of sponsored programs.

Fringe Benefits

Fringe benefits may be requested, in accordance with institutional guidelines for each position, provided the costs are treated consistently by the applicant organization as a direct cost to all sponsors.

Totals

Calculate the totals for each position and enter the subtotals in each column where indicated.

The applicant organization and its subcontractor(s) may omit salaries and fringe benefits for individuals from copies of the application that are available to non-Federal reviewers. In such cases, replace the numbers with asterisks. You must show the subtotals. Provide one copy, for use only by PHS staff, with the asterisks replaced by the salaries and fringe benefits.

Special Instructions for Individuals with Joint University and Department of Veterans Affairs Appointments

Individuals may request the university's share of their salary in proportion to the effort devoted to the research project. The individual's salary with the university determines the base for computing that request. Signature by the institutional official on the application certifies that: (1) the individual is applying as part of a joint appointment specified by a formal Memorandum of Understanding between the university and the Department of Veterans Affairs (VA); and (2) there is no possibility of dual compensation for the same work, or of an actual or apparent conflict of interest regarding such work.

For applications under joint-appointment conditions, do the following:

Type of Appointment/Months

List the number of months per year reflected in the university appointment. Identify with an asterisk (*) and provide a full explanation about the individual's total responsibilities under the joint appointment on Form Page 5. Specify the title of each appointment, the types of responsibilities (teaching, research, clinical, consulting, and administration) and the proportion of each to the total set of responsibilities.

Percent of Effort on Project

List the percentage of the university appointment that is to be devoted to this project.

For VA responsibilities, complete the type of appointment and percent of effort on a separate line.

Consultant Costs

Whether or not costs are involved, provide the names and organizational affiliations of all consultants, other than those involved in consortium/contractual arrangements. Include consultant physicians in connection with patient care and persons who serve on external monitoring boards or advisory committees to the project. Describe the services to be performed on Form Page 5 under Justification. Include the number of days of anticipated consultation, the expected rate of compensation, travel, per diem, and other related costs.

Equipment

List each item of equipment separately and justify each purchase on Form Page 5.

Supplies

Itemize supplies in separate categories, such as glassware, chemicals, radioisotopes, etc. Categories in amounts less than $1,000 do not have to be itemized. If animals are to be purchased, state the species and the number to be used.

Travel

Itemize travel requests and justify on Form Page 5. Provide the purpose and destination of each trip and the number of individuals for whom funds are requested.

Patient Care Costs

If inpatient and/or outpatient costs are requested, provide the names of any hospitals and/or clinics and the amounts requested for each on Form Page 5.

For research grants, state whether each hospital or clinic has a currently effective DHHS-negotiated research patient care rate agreement and, if not, what basis is used for calculating costs. If an applicant does not have a DHHS-negotiated rate, a provisional rate can be approved by the PHS awarding component. Indicate, in detail, the basis for estimating costs in this category, including the number of patient days, estimated cost per day, and cost per test or treatment. If both in-patient and out-patient costs are requested, provide information for each separately. If multiple sites are to be used, provide detailed information by site.

Include information regarding projected patient accrual for the project/budget periods and relate this information to the budget request for patient care costs. If patient accrual is anticipated to be lower at the start or during the course of the project, plan budget(s) accordingly.

Provide specific information regarding anticipated sources of other support for patient care costs, e.g., third party recovery or pharmaceutical companies. Include any potential or expected utilization of General Clinical Research Centers.

Alterations and Renovations

Itemize, by category and justify on Form Page 5, the costs of essential alterations and renovations including repairs, painting, removal or installation of partitions, shielding, or air conditioning. Where applicable, provide the square footage and costs. Costs for alterations and renovations are not allowed on grants made to foreign organizations.

Other Expenses

Itemize any other expenses by category and unit cost. These might include animal maintenance (unit care costs and number of care days), patient travel, donor fees, publication costs, computer charges, rentals and leases, equipment maintenance, service contracts, and tuition remission in lieu of salary. Justify costs on Form Page 5.

Consortium/Contractual Costs

Each participating consortium/contractual organization must submit a separate detailed budget for both the initial budget period (Form Page 4) and the entire proposed project period (Form Page 5).

Consortium arrangements may involve personnel costs, supplies, and other allowable costs, including Facilities and Administration (indirect) costs. Contractual costs for support services, such as the laboratory testing of biological materials, clinical services, or data processing, are occasionally sufficiently high to warrant a similar categorical breakdown of costs.

When Facilities and Administration (F&A) costs are requested by a consortium organization, enter the F&A costs in the F&A cost category for each supplementary budget. Provide the F&A cost base and rate. Leave the direct cost category blank.

For the applicant organization budget, list the sum of all consortium/contractual costs (direct and F&A). Insert additional page(s) after Form Page 5, numbering them sequentially. (Do not use 5a, 5b, 5c, etc.)

5. Budget for Entire Proposed Period of Support (Form Page 5-EE)

Enter the totals under each budget category for all additional years of support requested. Identify with an asterisk (*), and justify any significant increases or decreases from the initial year budget. Also, justify budgets with more than a standard escalation from the initial to the future year(s) of support.

6. Biographical Sketch (Form Page 6-FF)

This section must contain the biographical sketches of all **key personnel** following the order as listed on Form Page 2. Each biographical sketch must be no more than two pages.

7. Other Support (Format Page 7-GG)

Other support is defined as **all financial resources**, whether Federal, non-Federal, commercial or institutional, **available in direct support of an individual's research endeavors**, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards. No longer included are training awards, prizes, or gifts.

Explanation of Format

There is no "form page" for other support. Information on other support should be provided in the **format** shown, using continuation pages as necessary. Include the principal investigator's name at the top and number consecutively with the rest of the application. **The sample is intended to provide guidance regarding the type and extent of information requested.**

Information on active and pending other support is required for **key personnel**, excluding consultants. For individuals with no active or pending support, indicate "None." Neither the application under consideration nor the current PHS award for this project should be listed as other support.

If the support is provided under a consortium/subcontract arrangement or is part of a multiproject award, indicate the project number, principal investigator, and source for the overall project and provide all other information for the subproject only.

Instructions for Selected Items

Project Number: If applicable, include a code or identifier for the project.

Source: Identify the agency, institute, foundation, or other organization that is providing the support.

Major Goals: Provide a brief statement of the overall objectives of the project, subproject, or subcontract.

Dates of Approved/Proposed Project: Indicate the inclusive dates of the project as approved/proposed. For example, in the case of NIH support, provide the dates of the approved/proposed competitive segment.

Annual Direct Costs: In the case of an active project, provide the current year's direct cost budget. For a pending project, provide the proposed direct cost budget for the initial budget period.

Percent Effort: For an active project, provide the level of effort (even if unsalaried) as approved for the current budget period. For a pending project, indicate the level of effort as proposed for the initial budget period. In cases where an individual's appointment is divided into academic and summer segments, indicate the proportion of each devoted to the project.

Overlap: After listing all support, summarize for each individual any potential overlap with the active or pending projects and this application in terms of the science, budget, or an individual's committed effort. (See page 26, for definitions of the three types of overlap.) Any necessary resolution of overlap due to this application being funded will occur in conjunction with the applicant institution and awarding agency staff at the time of award.

8. Resources (Form Page 8-HH)

Follow the instructions on the form.

9. Research Plan

The Research Plan should include sufficient information needed for evaluation of the project, independent of any other document. Be specific and informative, and avoid redundancies.

Introduction
(Revised or Supplemental Applications Only)

All **revised** and **supplemental** applications must include an Introduction. Do not exceed three pages for revised applications or one page for supplemental applications.

Revised Application

A revised application will be returned without review if it does not comply with all of these requirements.

Note: NIH will no longer consider more than two amendments to an application and, regardless of the number of amendments, the NIH will not accept a revised (amended) application that is submitted later than two years beyond the date of the receipt of the initial, unamended application.

Before a revised application can be submitted, the principal investigator must have received the summary statement from the previous review. There must be substantial changes in the content of the application. The application must include an Introduction of not more than three pages that summarizes the substantial additions, deletions, and changes. The Introduction must also include responses to the criticisms and issues raised in the

summary statement. The changes in the Research Plan must be clearly marked by appropriate bracketing, indenting, or changing of typography, unless the changes are so extensive as to include most of the text. This exception should be explained in the Introduction. Do not underline or shade changes. The Preliminary Studies/Progress Report section should incorporate any work done since the prior version was submitted. Acceptance of a revised application automatically withdraws the prior version, since two versions of the same application cannot be simultaneously pending.

Competing Supplements

A competing supplemental application may be submitted to request support for a significant expansion of a project's scope or research protocol. Applications for competitive supplements are **not** appropriate when the sole purpose is to restore awards, administratively reduced by the funding agency, to the full SRG-recommended level. A supplemental application will **not** be accepted until after the original application has been awarded, and may not extend beyond the term of the current grant. The introduction to the supplemental application should provide an overall description of the nature of the supplement and how it will influence the specific aims, research design, and methods of the current grant. Any budgetary changes for the remainder of the project period of the current grant should be discussed under the budget justification. The body of the application should contain sufficient information from the original grant application to allow evaluation of the proposed supplement in relation to the goals of the original application.

If the supplemental application relates to a specific line of investigation presented in the original application that was not recommended for approval by the SRG, then the applicant must respond to the criticisms in the prior summary statement, and substantial revisions must be clearly evident and summarized in the introduction.

Research Plan

Organize Items a-d, to answer these questions: (1) What do you intend to do? (2) Why is the work important? (3) What has already been done? (4) How are you going to do the work? **Do not exceed 25 pages for Items a-d.** The PHS recommends the following format and page distribution. All tables, graphs, figures, diagrams, and charts must be included within the 25 page limit. Full-sized glossy photographs of material such as electron micrographs or gels may be included in the Appendix; however, a photocopy of each must also be included within the page limitations of the Research Plan (see Appendix, page 19). **The 25 page limit will be strictly enforced. Applications that exceed this limit or do not conform to the type size limitations (see page 6) will be returned without review.**

Notice of Proprietary Information

Applicants are discouraged from submitting information considered proprietary unless it is deemed essential for proper evaluation of the application. However, if the application contains information that the applicant organization considers to be trade secrets or information that is commercial or financial; or information that is confidential or privileged, identify the pages in the application which contain this information by marking those paragraphs or lines containing this information with an asterisk (*) in the left-hand margin and providing the page numbers before "a. Specific Aims."

When information in the application constitutes trade secrets or information that is commercial or financial, and confidential or privileged, it is furnished to the Government in confidence with the understanding that the information shall be used or disclosed only for evaluation of this application. If a grant is awarded as a result of or in connection with the submission of this application, the Government shall have the right to use or disclose the information to the extent authorized by law. This restriction does not limit the Government's right to use the information if it is obtained without restriction from another source.

Format and Page Distribution

The PHS recommends the following format and page distribution:

a. **Specific Aims.** List the broad, long-term objectives and what the specific research proposed in this application is intended to accomplish. State the hypotheses to be tested. **One page is recommended**.

b. **Background and Significance.** Briefly sketch the background leading to the present application, critically evaluate existing knowledge, and specifically identify the gaps which the project is intended to fill. State concisely the importance and health relevance of the research described in this application by relating the specific aims to

the broad, long-term objectives. **Two to three pages are recommended.**

c. **Preliminary Studies/Progress Report.** For **new** applications, use this section to provide an account of the principal investigator/program director's preliminary studies pertinent to the application information that will help to establish the experience and competence of the investigator to pursue the proposed project. The complete references to appropriate publications and manuscripts **submitted or accepted** for publication may be listed, and are not part of the page limitations. Five collated sets of no more than 10 such items of background material may be submitted in the appendix.

   A progress report is required for **competing continuation** and **supplemental** applications. Provide the beginning and ending dates for the period covered since the project was last reviewed competitively.

   Summarize the previous application's specific aims and the importance of the findings. Discuss any changes in the specific aims as a result of budget reductions.

   For **competing continuation** applications that involve human subjects, report on the enrollment of women and men and on the race and ethnicity of research participants in each relevant funded study and for studies that will be continued. The Inclusion Report Format (see pages 29-30) should be used in this section of the application. Also report on any subpopulations.

   Provide a succinct account of published and unpublished results, indicating progress toward their achievement.

   List the titles and complete references to all publications, manuscripts **submitted or accepted** for publication, patents, and other printed materials that have resulted from the project since it was last reviewed competitively. Up to 10 such publications may be included in the five collated sets of appendices.

   Do **not** complete or submit the Personnel Report with the application. When requested by the awarding component, use this form page, Personnel Report (Form JJ), to list **all key personnel for the current budget period**, salaried and unsalaried, at the applicant organization or elsewhere, who participated in the project during the current budget period. Include all degrees, role on project, date of birth, annual percent of effort, and Social Security number. When requesting Social Security numbers from personnel, explain that provision of the Social Security number is voluntary, and the information will be used only for program management purposes.

   Note: The publications and the personnel report are not included in the 25 page limit.

   Six to eight pages are recommended for the narrative portion of the Preliminary Studies/Progress Report.

d. **Research Design and Methods.** Describe the research design and the procedures to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted. Describe any new methodology and its advantage over existing methodologies. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. As part of this section, provide a tentative sequence or timetable for the project. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised.

   Gender and Minority Inclusion for Research Involving Human Subjects

   The NIH policy is that women and members of minority groups and their subpopulations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale shows that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances may be made based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This policy applies to research subjects of all ages.

Address the inclusion of women and members of minority groups and their subpopulations in developing a research design appropriate to the scientific objectives of the study. Describe the composition of the proposed study population in terms of gender and racial/ethnic group, and provide a rationale for selection of such subjects. Display this proposed composition using the Inclusion Report Format (see pages 29-30). Provide the proposed enrollment beginning and end dates. Include a description of proposed outreach programs for recruiting women and minorities as participants. Provide a compelling rationale and justification for requesting any exclusions noted above. When proposing Phase III clinical trials, show whether clinically important gender or race/ethnicity differences are to be expected, and the trial should be designed to accommodate any differences (see page 29).

Inclusion of Children as Participants in Research Involving Human Subjects

It is the NIH policy that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are clear and compelling reasons not to include them. Therefore, proposals for research involving human subjects must include a description of plans for including children. If children will be excluded from the research, the application or proposal must present an acceptable justification for the exclusion (see justifications for exclusions, pages 31-32).

In the research plan, the investigator should create a section titled "**Participation of Children.**" This section should provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. When children are included, the plan must also include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.

Although no specific number of pages is recommended for this section of the application, the total for Items a-d may not exceed 25 pages, including all tables and figures.

e. **Human Subjects.** If you have marked Item 4a on the Face Page "Yes" and designated exemptions from the human subjects regulations, **provide sufficient information** to allow a determination that the designated exemptions are appropriate. Research that is exempt from coverage under the regulations is discussed under Human Subjects (see pages 27-28). Even if a grant application is exempt from these regulations, it must, nevertheless, address the issues of gender/race/ethnic composition of the subject population as explained above.

   If you have marked Item 4 on the Face Page of the application "Yes," and designated no exemptions from the regulations, address the following six points. In addition, when research involving human subjects will take place at collaborating site(s) or other performance site(s), provide this information before discussing the six points. **Although no specific page limitation applies to this section of the application, be succinct.**

   (1) Provide a detailed description of the proposed involvement of human subjects in the work previously outlined in the Research Design and Methods section. Describe the characteristics of the subject population, including their anticipated number, age range, and health status. Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as fetuses, pregnant women, children, prisoners, institutionalized individuals, or others who are likely to be vulnerable.

   (2) Identify the sources of research material obtained from individually identifiable **living** human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

(3) Describe plans for the recruitment of subjects and the consent procedures to be followed. Include the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. State if the Institutional Review Board (IRB) has authorized a modification or waiver of the elements of consent or the requirement for documentation of consent. The informed consent form, which must have IRB approval, should be submitted to the PHS only if requested.

(4) Describe potential risks (physical, psychological, social, legal, or other) and assess their likelihood and seriousness. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.

(5) Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of subjects.

(6) Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result.

If a test article (investigational new drug, device, or biologic) is involved, name the test article and state whether the 30-day interval between submission of applicant certification to the Food and Drug Administration and its response has elapsed or has been waived and/or whether use of the test article has been withheld or restricted by the Food and Drug Administration.

f. **Vertebrate Animals.** If you have marked Item 5 on the Face Page of the application "Yes," address the following five points. In addition, when research involving vertebrate animals will take place at collaborating site(s) or other performance site(s), provide this information before discussing the five points. **Although no specific page limitation applies to this section of the application, be succinct.**

(1) Provide a detailed description of the proposed use of the animals in the work outlined in the Research Design and Methods section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.

(2) Justify the use of animals, the choice of species, and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.

(3) Provide information on the veterinary care of the animals involved.

(4) Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.

(5) Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association. If not, present a justification for not following the recommendations.

g. **Literature Cited.** List all references. The list may include, but may not replace, the list of publications required in the Progress Report for competing continuation applications.

Each reference must include the title, names of all authors, book or journal, volume number, page numbers, and year of publication. The reference should be limited to relevant and current literature. While there is no longer a page limitation, it is important

to be concise and to select only those literature references pertinent to the proposed research.

h. **Consortium/Contractual Arrangements.** Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s). If consortium/contractual activities represent a significant portion of the overall project, explain why the applicant organization, rather than the ultimate performer of the activities, should be the grantee.

   The consortium investigator and the authorized official at the consortium institution(s) must provide a signed statement or confirming letters that the appropriate programmatic and administrative personnel of each organization involved in the application are aware of the PHS consortium grant policy and are prepared to establish the necessary interinstitutional agreements consistent with that policy. The grantee institution has the specific responsibility for ensuring that all required assurances are obtained from the consortium.

i. **Consultants.** Attach appropriate letters here from all individuals confirming their roles in the project.

10. Appendix

Include five collated sets of all appendix material, in the same package with the application, following all copies of the application. Identify each item with the name of the principal investigator.

Do not use the appendix to circumvent the page limitations of the research plan. Graphs, diagrams, tables, and charts that do not need to be in a glossy format to show detail must not be included in the appendix. An application that does not observe these limitations may be returned. The appendix will not be duplicated with the application and will be sent only to certain members of the SRG who will serve as the primary reviewers of the application.

These appendix limitations may not apply to specialized grant applications. Request and follow the additional instructions for those applications.

For new, revised, and competing applications, the following materials may be included in the appendix:

(1) Up to 10 publications, manuscripts (submitted or accepted for publication), abstracts, patents, or other printed materials directly relevant to this project. These may be stapled as sets.

(2) Surveys, questionnaires, data collection instruments, and clinical protocols. These may be stapled as sets.

(3) Original glossy photographs or color images of gels, micrographs, etc., provided that a photocopy (may be reduced in size) is also included within the 25 page limit of items a-d of the research plan. **No photographs or color images may be included in the appendix that are not also represented within the Research Plan.**

11. Checklist (II)

a. Type of Application

Check all that apply.

Inventions and Patents (Competing Continuation Applications Only). If no inventions were conceived or reduced to practice during the course of work under this project, check “No.” The remaining parts of the item are then not applicable.

If any inventions were conceived or reduced to practice during the previous period of support, check “Yes.” Also indicate whether this information has been previously reported to the PHS or to the applicant organization official responsible for patent matters.

b. Assurances/Certifications

Each application to the PHS requires that the assurances and certifications listed on the Checklist be verified by the signature of the official signing for the applicant organization on the Face Page of the application.

c. Program Income

If no program income is anticipated during the period(s) for which grant support is requested, no other action is necessary.

If program income is anticipated, use the format provided. If the application

is funded, the Notice of Grant Award will provide specific instructions regarding the use of such income.

d. Facilities and Administration Costs

Follow the instructions on the Checklist.

e. Smoke-Free Workplace

Follow instructions on the Checklist. Response to the question has no impact on the review or funding of this application.

12. Personnel Report (For Competing Continuation Applications Only-JJ)

Use **only** when requested by the awarding component. Follow the competing continuation Progress Report instructions on page 16.

13. Personal Data (KK)

Self-explanatory.

SECTION II.
SUBMITTING YOUR APPLICATION

A. Instructions

Submit the following materials in one package:

(1) A cover letter if the principal investigator is making a request for assignment to a particular awarding component or initial review group. These suggestions will be taken into consideration at the time of assignment, although the final determination will be made by the PHS.

(2) The original application, single-sided, with both required signatures on the Face Page. Note that the pages must be assembled in the order specified in the table of contents. The Personal Data page should be placed at the end of the application; **it is not to be duplicated**. If appropriate, attach the RFA label provided in the application kit or a facsimile to the Face Page.

(3) Five exact, single-sided copies of the application. These should be made **after** both individuals have signed the Face Page.

(4) Five collated sets of Appendix material. Items should be stapled, where appropriate, and each marked with the name of the principal investigator. A summary sheet, listing all of the items included in the Appendix, is helpful.

Send the application to the following address:

CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
SUITE 1040
6701 ROCKLEDGE DRIVE MSC 7710
BETHESDA MD 20892-7710

If express mail or courier service is used, the zip code should be changed to 20817. The telephone number is (301) 435-0715.

There may be additional instructions for submission of responses to Requests for Applications.

Applicants submitting Investigator-Initiated Interactive Research Project Grant (IRPG) applications should include all of the components in one package.

The PHS uses the following receipt, review, and award schedule:

RECEIPT, REVIEW, AND AWARD CYCLES

	Types of Applications	Cycle I	Cycle II	Cycle III
Application Receipt Dates	**All** Institutional National Research Service Awards*	January 10	May 10	September 10
	New Research Grant, Conferences, and Research Career Awards. **All** (new, competing, revised and supplemental) Program Project* and Center Grants*	February 1	June 1	October 1
	Competing Continuation, Supplemental, and Revised Research Grants, Conferences, and Research Career Awards	March 1	July 1	November 1
	Interactive Research Project Grants (IRPGs)	February 15	June 15	October 15
	All AIDS-Related Grants	May 1	September 1	January 2
Review and Award Schedule	Scientific Merit Review	June–July	October–November	February–March
	Advisory Council Review	September–October	January–February	May–June
	Earliest Project Start Date	December	April	July

*For these specialized grant applications, consult with the appropriate PHS awarding component prior to the preparation of an application. Note that NIH applicants are required to contact Institute or Center program staff if requesting $500,000 or more in direct costs for any year.

An **unsolicited application** will be considered on time if it is received by or mailed on or before the published receipt date and a proof of mailing is provided. Proof of timely mailing consists of one of the following: a legibly-dated U.S. Postal Service postmark; or a dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks are not acceptable.

If a **receipt date** falls on a weekend, it will be extended to the following Monday; if the date falls on a holiday, it will be extended to the following work day.

Solicited applications must be **received** by the specified dates. However, an application received after the deadline may be acceptable if it carries a legible proof-of-mailing date, assigned by the carrier, and the proof-of-mailing date is not later than 1 week prior to the deadline date. These include Request for Applications (RFAs) and Program Announcements (PAs) with specified receipt dates.

The receipt date will be waived only in extenuating circumstances. To request a waiver, include an explanatory letter with the signed, completed application. **No request for a waiver will be considered prior to receipt of the application, and there is no guarantee that the waiver will be granted.**

Submit a complete application. An application will be returned if it is illegible, if the instructions were not followed, or if the material presented is insufficient to permit an adequate review. Unless specifically required by these instructions (e.g., human subjects certification, vertebrate animals verification, changes in other support), do not send supplementary or corrective material after the receipt date unless the scientific review administrator of the SRG solicits or agrees to accept this information. The application must be complete and accurate at the time of submission as there is no guarantee that late material will be considered.

Simultaneous submissions of identical applications to different agencies within the PHS or to different Institutes within an agency are not allowed. Essentially identical applications will not be reviewed except for: 1) individuals submitting an application for an Independent Scientist Award proposing essentially identical research in an application for an individual research project; and 2) individuals submitting an individual research project identical to a subproject that is part of a program project or center grant application.

As soon as possible after the receipt date, usually within 6 weeks, the PHS will send the principal investigator/program director and the applicant organization the application's assignment number; the name, address, and telephone number of the scientific review administrator of the Scientific Review Group (SRG) to which the application has been assigned; and the assigned Institute contact and phone number. If this information is not received within that time, contact the Division of Receipt and Referral, Center for Scientific Review (CSR), National Institutes of Health, Bethesda, MD 20892-7720, (301) 435-0715. If there is a change in assignment, another notification will be sent.

All inquiries regarding the assignment, review, or recommendation on funding of applications are to be made only to PHS officials. It is inappropriate to contact consultants serving on advisory or review committees regarding these issues.

B. The Peer Review Process

Most applications submitted to the PHS will be reviewed through a two-tier system. The first level of review will be performed by an SRG, often called a study section or review committee. The primary purpose of the SRG is to evaluate the scientific and technical merit of applications. The second level of review will usually be performed by the Advisory Council or Board of the potential awarding component (Institute, Center, or other unit). Council or Board recommendations are based not only on considerations of scientific merit, as judged by the SRGs, but also on the relevance of the proposed study to an Institute's programs and priorities. The review criteria can be found on the NIH Web site, http://www.nih.gov/grants/peer/peer.htm or obtained from GrantsInfo, (301) 435-0714, e-mail: GrantsInfo@nih.gov.

Grant applications submitted to the PHS agencies must be submitted through the Division of Receipt and Referral, CSR, NIH unless otherwise stated. Administrative information about the application is entered into a computer system. The application is then assigned to the appropriate SRG and Institute(s). Assignment is based on the scientific content of the application using established referral guidelines.

C. Interactions Before Submission

Additional information about the PHS peer review process and grant programs can be obtained from GrantsInfo, e-mail: GrantsInfo@nih.gov, (301) 435-0714. Information about charters and membership of SRGs, Councils, and Boards can be obtained from the appropriate agency.

Applicants are encouraged to contact relevant Institute staff for advice in preparing an application and for information regarding programmatic areas of interest. Phone numbers for contacting Institute staff are listed below:

NATIONAL INSTITUTES OF HEALTH	
Fogarty International Center	301-496-1653
National Cancer Institute	301-496-3428
National Human Genome Research Institute	301-496-7531
National Center for Research Resources	301-496-6023
National Eye Institute	301-496-5301
National Heart, Lung, and Blood Institute	301-435-0260
National Institute on Aging	301-496-9322
National Institute on Alcohol Abuse and Alcoholism	301-443-4375
National Institute of Allergy and Infectious Diseases	301-496-7291
National Institute of Arthritis and Musculoskeletal and Skin Diseases	301-594-2463
National Institute of Child Health and Human Development	301-496-0104
National Institute on Deafness and Other Communication Disorders	301-496-1804
National Institute of Dental Research	301-594-7710
National Institute of Diabetes and Digestive and Kidney Diseases	301-594-8834
National Institute on Drug Abuse	301-443-2755
National Institute of Environmental Health Sciences	919-541-7723
National Institute of General Medical Sciences	301-594-4499
National Institute of Mental Health	301-443-4335
National Institute of Neurological Disorders and Stroke	301-496-9248
National Institute for Nursing Research	301-594-5968
National Library of Medicine	301-496-4621
AGENCY FOR HEALTH CARE POLICY AND RESEARCH	301-594-1447
CENTERS FOR DISEASE CONTROL AND PREVENTION	
National Institute for Occupational Safety and Health	404-639-3343
Procurement and Grants Office	404-842-6630
FOOD AND DRUG ADMINISTRATION	301-827-7185
OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH	
Office of Adolescent Pregnancy Programs	301-594-4004
Office of Family Planning	301-594-4008

D. Interactions After Submission

Once the assignment has been made, the principal investigator/program director may request reassignment if the initial assignment seems inappropriate. Such requests should be made in writing to the Division of Receipt and Referral, Center for Scientific Review, National Institutes of Health, Suite 2030, 6701 Rockledge Drive, MSC 7720, Bethesda, MD 20892-7720. Although these requests will be carefully considered, the final determination will be made by the PHS agency.

SECTION III. OTHER INFORMATION

This section contains information on policy and additional guidance relating to submission of traditional, solicited and unsolicited, investigator-initiated, research project grant and cooperative agreement applications to PHS. Refer to the Foreword and the GrantsInfo information resources for additional sources of information.

A. Definitions

1. **AIDS Related:** Includes: (1) projects relating to the etiology, epidemiology, natural history, diagnosis, treatment, or prevention of AIDS; (2) various sequelae specifically associated with the syndrome; and (3) preparation and screening of anti-AIDS agents as well as vaccine development, including both preclinical and clinical studies. Not all applications examining various influences on T-lymphocytes or retroviruses will be appropriate for the expedited AIDS review process. Applications only indirectly related to AIDS will be evaluated by established SRGs (study sections) appropriate to the scientific discipline during regular NIH review cycles and should not be submitted in response to the expedited AIDS receipt dates. Applicants are urged to take note of the yearly NIH Plan for HIV-Related Research, and indicate how their application addresses the NIH priorities set forth in that Plan. The Plan can be found on the NIH Office of AIDS Research Home Page.

2. **Applicant Organization Types**

   Federal: A cabinet-level department or independent agency of the Executive Branch of the Federal Government or any component part of such a department or agency that may be assigned the responsibility for carrying out a grant-supported program.

   State: Any agency or instrumentality of a State government of any of the United States or its territories.

   Local: Any agency or instrumentality of a political subdivision of government below the State level.

   Nonprofit: An institution, corporation, or other legal entity no part of whose net earnings may lawfully inure to the benefit of any private shareholder or individual.

   Forprofit: An institution, corporation, or other legal entity which is organized for the profit or benefit of its shareholders or other owners. A “forprofit” organization is considered to be a small business if it is independently owned and operated, if it is not dominant in the field in which research is proposed, and if it employs no more than 500 persons.

3. **Collaborator:** An individual involved with the principal investigator in the scientific development or execution of the project. These individuals would typically devote a specific percent of effort to the project and would be identified as key personnel. The collaborator may be employed by, or affiliated with, either the grantee organization or an organization participating in the project under a consortium or contractual agreement.

4. **Consortium or Contractual Agreement:** An agreement whereby a research project is carried out by the grantee and one or more other organizations that are separate legal entities. In this arrangement, the grantee contracts for the performance of a substantial and/or a significant portion of the activities to be conducted under the grant. These agreements typically involve a specific percent of effort from the consortium organization’s principal investigator and a categorical breakdown of costs, such as personnel, supplies, and other allowable expenses, including Facilities and Administration costs.

5. **Consultant:** An individual hired to give professional advice or services for a fee, normally not as an employee of the hiring party. In unusual situations, a person may be both a consultant and an employee of the same party, receiving compensation for some services as a consultant and for other work as a salaried employee. In order to prevent apparent or actual conflicts of interest, grantees and consultants must establish written guidelines indicating the conditions of payment of consulting fees. Consultants may also include firms that provide paid professional advice or services.

   Consulting fees paid by an educational institution to a salaried member of its faculty are allowable only in unusual cases and only if both of the following conditions exist: (1) the consultation is across departmental lines or involves a separate operation; or (2) the work performed

by the consultant is in addition to his or her regular workload.

In all other cases, consulting fees paid to employees of recipient or cost-type contractor organizations in addition to salary may be charged to PHS grant-supported projects only in unusual situations and when all of the following conditions exist: (1) the policies of the recipient or contractor permit such consulting fee payments to its own employees regardless of whether Federal grant funds are received; (2) the consulting services are clearly outside the scope of the individual's salaried employment; and (3) it would be inappropriate or not feasible to compensate the individual for these services through payment of additional salary.

For additional clarification on the allowance and appropriateness of consulting fees, refer to the *PHS Grants Policy Statement.*

6. **Cooperative Agreement:** A support mechanism that will have substantial Federal scientific and/or programmatic involvement. Substantial programmatic involvement means that after award, scientific or program staff will assist, guide, coordinate, or participate in programmatic activities beyond the normal stewardship responsibility in the administration of grants. Proposed cooperative agreements will be published as policy announcements, program announcements, or requests for applications.

7. **Foreign Component:** (1) The use of grant funds to support any significant element or segment of the project which is to be performed outside the U.S., either by the grantee or by a researcher employed by a foreign institution; or (2) the use of grant funds for extensive foreign travel by grantee project staff for the purpose of data collection, surveying, sample collection, etc. Foreign travel for consultation is not considered a substantial foreign component.

8. **Full-Time Appointment:** May be different in terms of actual months per year or days per week at the applicant organization. The definition of a full-time appointment must be in accordance with the institutional policy and used consistently by the institution regardless of the source of support.

9. **Institutional Base Salary:** The annual compensation that the applicant organization pays for an employee's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of duties to the applicant organization. Base salary **may not** be increased as a result of replacing institutional salary funds with grant funds.

   Some PHS grant recipients are currently subject to a legislatively imposed salary limitation. Any adjustment for salary limits will be made at time of award. Applicants are encouraged to contact their offices of sponsored programs or see the *NIH Guide for Grants and Contracts* for current guidance on salary requirements.

10. **Key Personnel:** Key personnel are defined as, and should be limited to, individuals who contribute to the scientific development or execution of the project in a substantive way, whether or not salaries are requested. (For a more detailed discussion, see page 11.)

11. **Principal Investigator, Program Director, or Project Director:** The one individual designated by the applicant organization to direct the project or program to be supported by the grant. The principal investigator is responsible and accountable to applicant organization officials for the proper conduct of the project or program.

12. **Program Income:** Gross income earned by the applicant organization that is directly generated by a supported activity or earned as a result of the award. The *PHS Grants Policy Statement* contains a detailed explanation of program income, the ways in which it may be generated and accounted for, and the various options for its use and disposition.

    Examples of program income include:

    - Fees earned from services performed under the grant, such as those resulting from laboratory drug testing;
    - Rental or usage fees, such as those earned from fees charged for use of computer equipment purchased with grant funds;
    - Third party patient reimbursement for hospital or other medical services, such as insurance payments for patients when such

reimbursement occurs because of the grant-supported activity;

- Funds generated by the sale of commodities, such as tissue cultures, cell lines, or research animals; and
- Patent or copyright royalties.

B. Other Support

Other Support includes **all financial resources**, whether Federal, non-Federal, commercial or institutional, **available in direct support of an individual's research endeavors**, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards. No longer included are training awards, prizes, or gifts.

1. Other Support Policy

The information on other support assists awarding agency staff in the identification and resolution of potential overlap of support. Overlap, whether scientific, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. The goals in identifying and eliminating overlap are to ensure that sufficient and appropriate levels of effort are committed to the project; that there is no duplication of funding for scientific aims, specific budgetary items, or an individual's level of effort; and that funds not otherwise necessary to the conduct of the approved project are not included in the award.

The principal investigator is responsible for being aware of any changes in the other support of key personnel and for notifying the appropriate grants management office of such changes. Updated information on other support may be requested at the time of award when there is a substantial amount of pending support, when there has been a significant time lapse since the time of application, or when potential overlap has been identified.

Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salary) are requested in an application but are already funded or provided for by another source.

Commitment overlap occurs when any project personnel has time commitments exceeding 100 percent. This is the case whether or not the grant includes salary support for the effort. While information on other support is only requested for key personnel (excluding consultants), **no individuals on the project may have commitments in excess of 100 percent.**

Scientific Overlap occurs when: (1) substantially the same research is proposed in more than one application or is submitted to two or more different funding sources for review and funding consideration, or (2) a specific research objective and the research design for accomplishing that objective are the same or closely related in two or more applications or awards, regardless of the funding source.

2. Resolution of Overlap

Although applicants are requested to identify potential overlap, the actual resolution of overlap occurs at the time of award in conjunction with applicant institution officials, the principal investigator, and awarding agency staff. Potential overlap is to be addressed by the SRG *only* by its identification in an Administrative Note in the summary statement.

C. Grant Solicitations

Specific Program Announcements (PAs) and Requests for Applications (RFAs) are published in the *Federal Register* and in the *NIH Guide for Grants and Contracts*. The *Guide* also contains vital information about policies and procedures. For information on obtaining the *Guide*, see page 3. Definitions regarding the use of PAs and RFAs are as follows:

Program Announcement: A formal statement about a new or ongoing extramural activity or mechanism. It may serve as a reminder of continuing interest in a research area, describe modification in an activity or mechanism, and/or invite applications for grant support. Most applications in response to PAs may be submitted for any appropriate receipt date and are reviewed with all other applications received at that time.

Request for Applications: A formal statement that invites grant or cooperative agreement applications in a well-defined scientific area to accomplish specific program objectives. The RFA indicates the estimated amount of funds set aside for the competition, the estimated number of awards to be made, and the application receipt date(s). Applications submitted in response to an RFA usually are reviewed by an SRG convened by the awarding component that issued the RFA.

D. Start Dates

Awarding components may not always be able to honor the requested start date of an application. Therefore, applicants should make no commitments or obligations until confirmation of the start date by the awarding component.

E. Inventions and Patents

NIH recipient organizations must promptly report inventions to the Extramural Inventions and Technology Resources Branch of the Office of Policy for Extramural Research Administration, OER, NIH, Bethesda, MD 20892-2750, (301) 435-1986. This should be done **prior** to any publication or presentation of the invention at an open meeting, since failure to report at the appropriate time is a violation of 35 USC 202 and may result in loss of the rights of the applicant institution, inventor, and Federal Government in the invention. All foreign patent rights are immediately lost upon publication or other public disclosure unless a United States patent application is already on file. In addition, statutes preclude obtaining valid United States patent protection after one year from the date of a publication that discloses the invention.

F. Assurances and Certifications

The assurances listed below may not be applicable to your project, program, or type of applicant organization. Refer to the *PHS Grants Policy Statement* for further clarification about applicability, or contact the awarding agency. A copy of the *PHS Grants Policy Statement* may be obtained from the NIH Web site or requested from GrantsInfo, (301) 435-0714, e-mail: GrantsInfo@nih.gov. **In signing the application Face Page, the duly authorized representative of the applicant organization certifies that the applicant organization will comply with the following:**

1. Human Subjects

The DHHS regulations for the protection of human subjects provide a systematic means, based on established, internationally recognized ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the DHHS. The regulations stipulate that an applicant organization, whether domestic or foreign, bears responsibility for safeguarding the rights and welfare of human subjects in DHHS-supported research activities. The regulations require that applicant organizations proposing to involve human subjects in nonexempt research, file a written Assurance of Compliance with the Office for Protection from Research Risks (OPRR), establishing appropriate policies and procedures for the protection of human subjects. These regulations, 45 CFR 46, Protection of Human Subjects, are available from the OPRR, National Institutes of Health, Rockville, MD 20892, (301) 496-7041.

The regulations define “human subject” as “a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information.” The regulations extend to the use of human organs, tissues, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable state and local law and is not directly regulated by 45 CFR 46.

Research activities in which the only involvement of human subjects will be in one or more of the following six categories are exempt from coverage by the regulations:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (b) any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph(2)(b) of this section, if: (a) the human subjects are elected or appointed public officials or candidates for public office; or (b) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (a) if wholesome foods without additives are consumed or (b) if a food is consumed that contains a food ingredient at or below the level and use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Investigators who conduct research involving fetuses, pregnant women, children, human in vitro fertilization, or prisoners, must follow the provisions of the regulations in Subparts B, C, and D of 45 CFR 46, which describe the additional protections required for these subjects.

No DHHS award for nonexempt research involving human subjects will be made to an applicant organization unless that organization is operating in accord with an approved Assurance of Compliance and provides certification that an appropriate Institutional Review Board (IRB) has reviewed and approved the proposed activity in accordance with the DHHS regulations. No award to an individual will be made unless that individual is affiliated with an assured organization that accepts responsibility for compliance with the DHHS regulations. Foreign applicant organizations must also comply with the provisions of the regulations.

The Center of Biologics Evaluation and Research (CBER), FDA, regulates the use of biological products in humans, at the investigational and marketing phases, including somatic cell therapies and gene therapies. If your work involves these areas or preclinical research which will support later work in these areas, please see the Office of Recombinant DNA Activities Web site at http://www.nih.gov/od/orda.

a. Research on Transplantation of Fetal Tissue

In signing the application Face Page, the duly authorized representative of the applicant organization certifies that if research on the transplantation of human fetal tissue is conducted, the applicant organization will make available, for audit by the Secretary, DHHS, the physician statements and informed consents required by section 498A (b)(2) and (c) of the Public Health Service Act, 42 U.S.C. 289g (b)(2) and (c), or ensure DHHS access to those records, if maintained by an entity other than the applicant organization.

b. Gender and Minority Inclusion Policy

Research involving human subjects must comply with the “NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research.” The following excerpts provide the key policy statements. Investigators should obtain full copies of the Guidelines from NIH staff, the *NIH Guide for Grants and Contracts* (March 18, 1994, Volume 23, Number 11) or the *Federal Register* (59FR 11146-11151). The NIH Guide can be found at http://www.nih.gov/grants/guide.

Research Involving Human Subjects

The policy of NIH is that women and members of minority groups and their subpopulations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification establishes inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances may be made based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. All NIH-supported biomedical and behavioral research involving human subjects is defined as clinical research. This policy applies to research subjects of all ages.

The inclusion of women and members of minority groups and their subpopulations must be addressed in developing a research design appropriate to the scientific objectives of the study. Describe the composition of the proposed study population in terms of gender and racial/ethnic group, and provide a rationale for selection of such subjects. Include a description of the proposed outreach programs for recruiting women and minorities as participants.

Funding

Awards will not be made if the research project does not comply with this policy. In addition, awardees must report annually on enrollment of women and men, and on the race and ethnicity of research participants in the Inclusion Report Format shown on the following page.

Additional Information

In conducting peer review for scientific and technical merit, SRGs must evaluate proposed plans for inclusion of minorities and both genders, the design of clinical trials, and recruitment/outreach as part of the scientific assessment and assigned score.

Under DHHS regulations to protect human subjects from research risks, certain research areas are exempt from these regulations (Exemptions 1-6). Nonetheless, NIH-supported biomedical and behavioral research projects involving human subjects that are exempt from the human subjects regulations should still address the inclusion of women and minorities in the study design. Therefore, all biomedical and behavioral research projects involving human subjects will be evaluated for compliance with this policy. For example, research involving the collection or study of existing data, documents, records, pathological specimens, diagnostic specimens, or tissues that are individually identifiable should also be included within the term “research involving human subjects.”

Inclusion Report Format

The following definitions apply for the racial and ethnic categories.

(1) Minority Groups

A minority group is a readily identifiable subset of the U.S. population which is distinguished by either racial, ethnic, and/or cultural heritage.

The Office of Management and Budget (OMB) Directive No. 15 defines racial and ethnic categories. NIH has chosen to use these definitions because they allow comparisons to many national databases, especially national health databases.

American Indian or Alaskan Native: A person having origins in any of the original peoples of North America, and who maintains cultural identification through tribal affiliation or community recognition.

Asian or Pacific Islander: A person having origins in any of the original peoples of the Far East, Southeast Asia, the Indian subcontinent, or the Pacific Islands. This area includes, for example, China, India, Japan, Korea, the Philippine Islands, and Samoa.

Black, not of Hispanic Origin: A person having origins in any of the black racial groups of Africa.

Hispanic: A person of Mexican, Puerto Rican, Cuban, Central or South American,

or other Spanish culture or origin, regardless of race.

(2) Majority Group

White, not of Hispanic Origin: A person having origins in any of the original peoples of Europe, North Africa, or the Middle East.

NIH recognizes the diversity of the U.S. population and that changing demographics are reflected in the changing racial and ethnic composition of the population. The terms "minority groups" and "minority subpopulations" are meant to be inclusive, rather than exclusive, of differing racial and ethnic categories.

(3) Subpopulations

Each minority group contains subpopulations, which are delimited by geographic origins, national origins and/or cultural differences. It is recognized that there are different ways of defining and reporting racial and ethnic subpopulation data. The subpopulation to which an individual is assigned depends on self-reporting of specific racial and ethnic origin. Attention to subpopulations also applies to individuals of mixed racial and/or ethnic parentage. Researchers should be cognizant of the possibility that these racial/ethnic combinations may have biomedical and/or cultural implications related to the scientific question under study.

INCLUSION REPORT FORMAT FOR EACH STUDY

Initially: Provide the number of subjects proposed for the study according to the following categories. If there is more than one study, provide a separate table for each study. In addition, report on the subpopulations that are proposed to be included in the study.

Annually: Provide the number of subjects enrolled in the study to date, according to the following categories. If there is more than one study, provide a separate table for each study. In addition, report on the subpopulations that are included in the study.

GENDER AND MINORITY INCLUSION
STUDY TITLE:

	American Indian or Alaskan Native	Asian or Pacific Islander	Black, not of Hispanic Origin	Hispanic	White, not of Hispanic Origin	Other or Unknown	Total
Female							
Male							
Unknown							
Total							

c. Inclusion of Children Policy

Research involving children must comply with the "**NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects,**" issued March 6, 1998. The following excerpts provide the key policy statements. Investigators should obtain full copies of the Policy and Guidelines from NIH staff, or from the NIH grants Web site under the *NIH Guide for Grants and Contracts* (http://www.nih.gov/grants/guide/notice-files/not98-024.html).

Research Involving Children

NIH policy is that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are clear and compelling reasons not to include them. This policy applies to all NIH conducted or supported research involving human subjects, including research that is otherwise "exempt" in accord with Section 401 (b) of 45 CFR 46 Subpart A - Federal Policy for the Protection of Human Subjects. The inclusion of children as subjects in research must be in compliance with all applicable subparts of 45 CFR 46 as well as with other pertinent federal laws and regulations. Therefore, proposals for research involving human subjects must include a description of plans for including children. If children will be excluded from the research, the application or proposal must present an acceptable justification for the exclusion.

In the research plan, the investigator should create a section titled "Participation of Children." This section should provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. When children are included, the plan must also include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study. Scientific review groups at the NIH will assess each application as being "acceptable" or "unacceptable" in regard to the age-appropriate inclusion or exclusion of children in the research project.

Justifications for Exclusions

It is expected that children will be included in all research involving human subjects unless one or more of the following exclusionary circumstances can be fully justified:

1. The research topic to be studied is irrelevant to children.

2. There are laws or regulations barring the inclusion of children in the research.

3. The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be redundant. Documentation of other studies justifying the exclusions should be provided. NIH program staff can be contacted for guidance on this issue if the information is not readily available.

4. A separate, age-specific study in children is warranted and preferable. Examples include:

   a. The relative rarity of the condition in children, as compared to adults (in that extraordinary effort would be needed to include children, although in rare diseases or disorders where the applicant has made a particular effort to assemble an adult population, the same effort would be expected to assemble a similar child population with the rare condition);

   b. The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network;

   c. Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children (including different cognitive, developmental, or disease stages or different age-related metabolic processes). While this situation may represent a justification for

excluding children in some instances, consideration should be given to taking these differences into account in the study design and expanding the hypotheses tested, or the interventions, to allow children to be included rather than excluding them.

5. Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment). While children usually should not be the initial group to be involved in research studies, in some instances, the nature and seriousness of the illness may warrant their participation earlier based on careful risk and benefit analysis.

6. Study designs aimed at collecting additional data on pre-enrolled adult study participants (e.g., longitudinal follow-up studies that did not include data on children).

7. Other special cases justified by the investigator and found acceptable to the review group and the Institute Director.

Definition of a Child

For the purpose of implementing these guidelines, the following definition of a child applies:

> A child is an individual under the age of 21 years.
>
> It should be noted that the definition of child described above will pertain notwithstanding the FDA definition of a child as an individual from infancy to 16 years of age, and varying definitions employed by some states. Generally, State laws define what constitutes a "child," and such definitions dictate whether or not a person can legally consent to participate in a research study. However, State laws vary, and many do not address when a child can consent to participate in research. Federal Regulations (45 CFR 46, subpart D, Sec.401-409) address DHHS protections for children who participate in research, and rely on State definitions of "child" for consent purposes. Consequently, the children included in this policy (persons under the age of 21) may differ in the age at which their own consent is required and sufficient to participate in research under State law. For example, some states consider a person age 18 to be an adult and therefore one who can provide consent without parental permission.
>
> Additionally, IRBs have special review requirements to protect the well-being of children who participate in research. These requirements relate to risk, benefit, parental/guardian consent, and assent by children, and to research involving children who are wards of the State or of another institution. The local IRB approves research that satisfies the conditions set forth in the regulations.

2. Vertebrate Animals

The PHS *Policy on Humane Care and Use of Laboratory Animals* requires that applicant organizations proposing to use vertebrate animals file a written Animal Welfare Assurance with the Office for Protection from Research Risks, establishing appropriate policies and procedures to ensure the humane care and use of live vertebrate animals involved in research activities supported by the PHS. The PHS policy stipulates that an applicant organization, whether domestic or foreign, bears responsibility for the humane care and use of animals in PHS-supported research activities. This policy implements and supplements the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training*, and requires that institutions use the *Guide for the Care and Use of Laboratory Animals* as a basis for developing and implementing an institutional animal care and use program. This policy does not affect applicable State or local laws or regulations that impose more stringent standards for the care and use of laboratory animals. All institutions are required to comply, as applicable, with the Animal Welfare Act as amended (7 USC 2131 et sec.) and other Federal statutes and regulations relating to animals. These documents are available from the Office for Protection from Research Risks, National Institutes of Health, Bethesda, MD 20892, (301) 496-7163.

The PHS policy defines "animal" as "any live, vertebrate animal used or intended for use in research, research training, experimentation or biological testing or for related purposes."

No PHS award for research involving vertebrate animals will be made to an applicant organization unless that organization is operating in accordance with an approved Animal Welfare Assurance and provides verification that the Institutional Animal Care and Use Committee (IACUC) has reviewed and approved the proposed activity in accordance with the PHS policy. Applications may be referred by the PHS back to the IACUC for further review in the case of apparent or potential violations of the PHS policy. No award to an individual will be made unless that individual is affiliated with an assured organization that accepts responsibility for compliance with the PHS policy. Foreign applicant organizations applying for PHS awards for activities involving vertebrate animals are required to comply with PHS policy or provide evidence that acceptable standards for the humane care and use of animals will be met.

3. Debarment and Suspension

Executive Order 12549, "Debarment and Suspension," mandated development of a Government-wide debarment and suspension system for nonprocurement transactions with Federal agencies. Executive Order 12689 and Section 2455 of the Federal Acquisition Streamlining Act of 1994 further required Federal agencies to establish regulations for reciprocal Government-wide effect across procurement and nonprocurement debarment and suspension actions. This reciprocity rule is effective for any debarment, suspension or other Government-wide exclusion initiated on or after August 25, 1995. DHHS regulations implementing Executive Orders 12549 and 12689, and Section 2455 of the Federal Acquisition Regulation, are Provided in 45 CFR 76, "Government-wide Debarment and Suspension (Nonprocurement) and Government-wide Requirements for Drug-Free Workplace (Grants)." Accordingly, before a grant award can be made, the applicant organization must make the following certification (Appendix A of the DHHS regulations):

"(1) The prospective primary participant certifies to the best of its knowledge and belief, that it and its principals (including research personnel):

"(a) Are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded by any Federal department or agency;

"(b) Have not within a three-year period preceding this proposal been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;

"(c) Are not presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State, or local) with commission of any of the offenses enumerated in paragraph (1)(b) of this certification; and

"(d) Have not within a three-year period preceding this application/proposal had one or more public transactions (Federal, State, or local) terminated for cause or default.

"(2) Where the prospective primary participant is unable to certify to any of the statements in this certification, such prospective participant shall attach an explanation to this proposal."

Grantees are required to obtain a similar certification from most subawardees, called "lower tier participants." (See 45 CFR 76, Appendices A and B.)

4. Drug-Free Workplace

The Drug-Free Workplace Act of 1988 (Public Law 100-690, Title V, Subtitle D) requires that all grantees receiving grants from any Federal agency certify to that agency that they will maintain a drug-free workplace. DHHS regulations implementing the Act are provided in 45 CFR 76, "Government-wide Debarment and Suspension (Nonprocurement) and Government-wide Requirements for Drug-Free Workplace (Grants)."

Accordingly, before a grant award can be made, the applicant organization must make the certification set forth below (Appendix C of the DHHS regulations). The certification is a material representation of fact upon which reliance will be placed by the PHS awarding component. False certification or violation of the certification shall be grounds for suspension of payments, suspension or termination of grants, or Government-wide suspension or debarment.

The applicant organization certifies "that it will continue to provide a drug-free workplace by:

"(a) Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession or use of a controlled substance is prohibited in the grantee's workplace and specifying the actions that will be taken against employees for violation of such prohibition;

"(b) Establishing an ongoing drug-free awareness program to inform employees about:

(1) The dangers of drug abuse in the workplace;

(2) The grantee's policy of maintaining a drug-free workplace;

(3) Any available drug counseling, rehabilitation, and employee assistance programs, and

(4) The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace;

"(c) Making it a requirement that each employee to be engaged in the performance of the grant be given a copy of the statement required by paragraph (a);

"(d) Notifying the employee in the statement required by paragraph (a) that, as a condition of employment under the grant, the employee will:

(1) Abide by the terms of the statement; and

(2) Notify the employer in writing of his or her conviction for a violation of a criminal drug statute occurring in the workplace no later than 5 calendar days after such conviction;

"(e) Notifying the agency in writing within 10 calendar days after receiving notice under subparagraph (d)(2) from an employee or otherwise receiving actual notice of such conviction. Employers of convicted employees must provide notice, including position title, to every grant officer or other designee on whose grant activity the convicted employee was working, unless the Federal agency has designated a central point for the receipt of such notices. Notice shall include the identification number(s) of each affected grant;

"(f) Taking one of the following actions, within 30 calendar days of receiving notice under subparagraph (d)(2), with respect to any employee who is so convicted:

(1) Taking appropriate personnel action against such an employee, up to and including termination, consistent with the requirements of the Rehabilitation Act of 1973, as amended; or

(2) Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;

"(g) Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (a), (b), (c), (d), (e), and (f)"

For purposes of paragraph (e), regarding agency notification of criminal drug convictions, the DHHS has designated the following central point for receipt of such notices:

Division of Grants Management
and Oversight
Office of Management and Acquisition
Department of Health and Human Services
Room 517-D
200 Independence Avenue, S.W.
Washington, DC 20201

5. Lobbying

Title 31, United States Code, Section 1352, entitled "Limitation on Use of Appropriated Funds to Influence Certain Federal Contracting and Financial Transactions," generally prohibits recipients of

Federal grants and cooperative agreements from using Federal (appropriated) funds for lobbying the Executive or Legislative Branches of the Federal Government in connection with a specific grant or cooperative agreement. Section 1352 also requires that each person who requests or receives a Federal grant or cooperative agreement must disclose lobbying undertaken with non-Federal (nonappropriated) funds. These requirements apply to grants and cooperative agreements **exceeding** $100,000 in total costs. DHHS regulations implementing Section 1352 are provided in 45 CFR Part 93, "New Restrictions on Lobbying."

The complete Certification Regarding Lobbying is provided below.

"The undersigned (authorized official signing for the applicant organization) certifies, to the best of his or her knowledge and belief that:

"(1) No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

"(2) If any funds other than Federally appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit Standard Form LLL, "Disclosure of Lobbying Activities," in accordance with its instructions.

"(3) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

"This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure."

Standard Form LLL, "Disclosure of Lobbying Activities," its instructions, and continuation sheet are available from GrantsInfo, National Institutes of Health, e-mail: GrantsInfo@nih.gov, (301) 435-0714.

6. Delinquent Federal Debt

In accordance with OMB Memorandum M-87-32, "Certification of Nondelinquency by Applicants for Federal Assistance," the applicant organization must certify that it is not delinquent on the repayment of any Federal debt before a grant award can be made. The certification applies to the applicant organization, not to the person signing the application as the authorized representative nor to the principal investigator.

Where the applicant discloses delinquency on debt to the Federal Government, the PHS shall (1) take such information into account when determining whether the prospective grantee organization is responsible with respect to that grant, and (2) consider not making the grant until payment is made or satisfactory arrangements are made with the agency to whom the debt is owed. Therefore, it may be necessary for the PHS to contact the applicant before a grant can be made to confirm the status of the debt and ascertain the payment arrangements for its liquidation. Applicants who fail to liquidate indebtedness to the Federal Government in a businesslike manner place themselves at risk of not receiving financial assistance from the PHS.

Federal debt collection provisions contained in Section 3201 (e) of the Federal Debt Collection Procedures Act also apply to individuals. PHS will disallow costs charged to awards that provide funds to individuals who are in violation of the Act.

7. Research Misconduct

Each institution that receives or applies for a research, research training, or research-related grant or cooperative agreement under the Public Health Service Act must certify that the institution has established administrative policies as required by (1) 42 CFR Part 50, Subpart A, "Responsibilities for PHS Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science," and (2) 42 CFR 94, "Public Health Service Standards for the Protection of Research Misconduct Whistleblowers" (effective on the date set forth in the final rule). Further, each covered institution must certify that it will comply with those policies and the requirements of the Final Rule.

The signature of the official signing for the applicant organization on the Face Page of the application serves as certification that:

(a) The institution will comply with the requirements of the PHS regulations for dealing with reporting possible scientific misconduct under 42 CFR Part 50, Subpart A, and for protecting research misconduct whistleblowers under 42 CFR Part 94;

(b) The institution has established policies and procedures incorporating the provisions set forth in 42 CFR Part 50, Subpart A, and 42 CFR Part 94;

(c) The institution will provide its policies and procedures to the Office of Research Integrity upon request; and

(d) The institution will submit an Annual Report on Possible Research Misconduct (Form 6349). A copy of Form 6349, covering the previous year, will be automatically sent to all PHS awardees by the Office of Research Integrity each January.

"Misconduct in Science" and "Research Misconduct" are defined by the Public Health Service as "fabrication, falsification, plagiarism or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research. It does not include honest error or honest differences in interpretation or judgments of data."

For further information, contact the Office of Research Integrity, Division of Policy and Education, Rockwall II, Suite 700, 5515 Security Lane, Rockville, MD 20852, (301) 443-5300, Fax: (301) 594-0042 or (301) 445-5351.

8. Assurance of Compliance (Civil Rights, Handicapped Individuals, Sex Discrimination, Age Discrimination)

Before a grant award can be made, a domestic applicant organization must certify that it has filed with the DHHS Office for Civil Rights: an Assurance of Compliance (Form HHS 690) with Title VI of the Civil Rights Act of 1964 (P.L. 88352, as amended), which prohibits discrimination on the basis of race, color, or national origin; Section 504 of the Rehabilitation Act of 1973 (P.L. 93-112, as amended), which prohibits discrimination on the basis of handicaps; Title IX of the Education Amendments of 1972 (P.L. 92-318, as amended), which prohibits discrimination on the basis of sex; and the Age Discrimination Act of 1975 (P.L. 94-135), which prohibits discrimination on the basis of age.

The Assurance of Compliance Form HHS 690 is available from GrantsInfo, e-mail: GrantsInfo@nih.gov, (301) 435-0714. (Note: Assurance of Compliance Form HHS 690 is now used in lieu of individual assurances: Form HHS 441, Civil Rights; Form HHS 641, Handicapped Individuals; Form HHS 639-A, Sex Discrimination; and Form HHS 680, Age Discrimination.)

9. Financial Conflict of Interest

Each institution that applies for a research, research training, or research-related grant or cooperative agreement under the Public Health Service Act must certify that the institution has established administrative policies as required by the Final Rule, 42 CFR Part 50, Subpart F. "Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought."

The signature of the official signing for the applicant institution on the Face Page of the application serves as certification that:

(a) There is in effect at that institution an administrative process to identify and resolve conflicting financial interests of the type described in Subpart 50.605(a)

with respect to all research projects for which funding is sought from the PHS;

(b) The institution agrees to make information available to the PHS regarding all conflicting financial interests identified by the institution of the type described in Subpart 50.605 and how those interests have been resolved to protect the research from bias; and

(c) The institution will otherwise comply with 42 CFR Part 50, Subpart F.

Significant Financial Interests means anything of monetary value, including but not limited to salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights (e.g., patents, copyrights, and royalties from such rights). The term does not include:

(i) Salary, royalties, or other remuneration from the institution;

(ii) Any ownership interests in the institution, if the institution is an applicant under the SBIR Program;

(iii) Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;

(iv) Income from service on advisory committees or review panels for public or nonprofit entities;

(v) An equity interest which meets both of the following tests: does not exceed $10,000 in value as determined through reference to public prices or other reasonable measures of fair value market when aggregated for the investigator and the investigator's spouse and dependent children; and constitutes more than a five percent ownership interest in any single entity when aggregated in the same manner; or

(vi) Salary, royalties, or other payments that are not reasonably expected to exceed $10,000 per annum from any single entity when aggregated for the investigator and the investigator's spouse and dependent children.

However, the exclusions in paragraphs (i), (v), and (vi) shall not apply if the compensation or transfer of an equity interest is conditioned upon a particular outcome in the PHS-funded research.

There are a number of additional public policy requirements with which applicants and grantees must comply. Refer to your institution's research grant administrative office or the *PHS Grants Policy Statement* for additional information.

G. PHS Metric Program

Consistent with Government-wide implementing regulations, 15 CFR Part 19, Subpart B and/or any other Government-wide requirements, PHS policy is to support Federal transition to the metric system and to use the metric system of measurement in all grants, cooperative agreements, and all other financial assistance awards. Likewise, measurement values in reports, publications, and other communications regarding grants will be in metric.

H. Smoke-Free Workplace

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

I. Prohibition on Awards to 501(c)4 Organizations That Lobby

Organizations described in section 501(c)4 of the Internal Revenue Code of 1968 that engage in lobbying are not eligible to receive grant/cooperative agreement awards. This is not to be confused with 45 CFR Part 93, Section 1352, "New Restrictions on Lobbying" shown on pages 34-35.

J. Government Use of Information Under Privacy Act

The Privacy Act of 1974 (5 U.S.C. 552a) is a records management statute and regulates the collection, maintenance, use, and dissemination of personal information by Federal agencies. In accordance with the Act, the PHS is required to provide the following notification to each individual whom it asks to supply information.

The PHS maintains applications and grant records pursuant to its statutory authority for awarding grants. The purpose of the information collection is to aid in the review, award, and administration of PHS programs. Provision of information is voluntary; however, a lack of sufficient information may hinder PHS's ability to review applications, monitor grantee performance, or perform overall management of grant programs.

The Privacy Act authorizes discretionary disclosure of this information within the Department of Health and Human Services and outside the agency to the public, as required by the Freedom of Information Act and the associated DHHS regulations (45 CFR 5), including the Congress acting within its legislative authority, the National Archives, the General Accounting Office, the Bureau of Census, law enforcement agencies, and pursuant to a court order. Information may also be disclosed outside the Department, if necessary, for the following purposes:

1. To a Congressional office at the request of the record subject;
2. To the Department of Justice as required for litigation;
3. To the cognizant audit agency for auditing;
4. To qualified experts not within the definition of Department employees as prescribed in Department Regulations (45 CFR 5b.2) for opinions as part of the application review/award process;
5. For an authorized research purpose under specified conditions;
6. To contractors for the purpose of processing, maintaining, and refining records in the system. Contractors will be required to maintain Privacy Act safeguards with respect to such records;
7. To a Federal agency, in response to its request, in connection with the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the records are relevant and necessary to the requesting agency's decision on the matter; and
8. To the applicant organization in connection with the review of an application or performance or administration under the terms and conditions of the award, or in connection with problems that might arise in performance or administration if an award is made.

K. Information Available to the Principal Investigator

Under the provisions of the Privacy Act, principal investigators may request copies of records pertaining to their grant applications from the PHS component responsible for funding decisions. Principal Investigators are given the opportunity under established procedures to request that the records be amended if they believe they are inaccurate, untimely, incomplete, or irrelevant. If the PHS concurs, the records will be amended.

L. Information Available to the General Public

The PHS makes information about awarded grants available to the public, including the title of the project, the grantee institution, the principal investigator, and the amount of the award. The description, on Form Page 2, of a funded research grant application is sent to the National Technical Information Service (NTIS), U.S. Department of Commerce, where the information is used for the dissemination of scientific information and for scientific classification and program analysis purposes. These descriptions are available to the public from the NTIS.

The Freedom of Information Act and implementing DHHS regulations (45 CFR Part 5) require the release of certain information about grants, upon request, irrespective of the intended use of the information. Trade secrets and commercial, financial, or otherwise intrinsically valuable information that is obtained from a person or organization and that is privileged or confidential information may be withheld from disclosure. Information which, if disclosed, would be a clearly unwarranted invasion of personal privacy may also be withheld from disclosure. Although the grantee institution and

the principal investigator will be consulted about any such release, the final determination will be made by the PHS. Generally available for release, upon request, except as noted above, are: all funded grant applications **including** their derivative funded **noncompeting supplemental** grant applications; pending and funded **noncompeting continuation** applications; progress reports of grantees; and final reports of any review or evaluation of grantee performance conducted or caused to be conducted by the DHHS. Generally, not available for release to the public are: **competing** grant applications (initial, competing continuation, and supplemental) for which awards have **not** been made; evaluative portions of site visit reports; and summary statements of findings and recommendations of review groups.

M. Recombinant DNA

The current *NIH Guidelines for Research Involving Recombinant DNA Molecules* and announcements of modifications and changes to the Guidelines are available on the NIH Web site at http://www.nih.gov/od/orda or from the Office of Recombinant DNA Activities, National Institutes of Health, Bethesda, MD 20892, (301) 496-9838. All research involving recombinant DNA techniques that is supported by the DHHS must meet the requirements of these Guidelines. As defined by the Guidelines, recombinant DNA molecules are either: (1) molecules which are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell; or (2) DNA molecules that result from the replication of those described in (1) above.

N. GrantsInfo Information Resources

A partial list of the NIH program guidelines and other publications are available on the NIH Web site and from GrantsInfo, e-mail: GrantsInfo@nih.gov, (301) 435-0714.

Extramural Program Guidelines

(1) *NIH National Research Service Award Institutional Grant (T32) Guidelines*

These awards are made to domestic institutions that have the facilities and faculty to provide for research training programs in scientific specialties. Grant funds may be used for personnel, equipment, supplies, trainee stipends (both pre and postdoctoral), and related costs. (Applicants should use the T32 guidelines with the PHS 398 application to apply for support.)

(2) *NIH National Research Service Award Senior Fellowship (F33) Guidelines*

Investigators who hold a doctorate or equivalent degree and have had at least 7 subsequent years of relevant research or professional experience may apply for senior fellowships. The award is designed to provide opportunities for experienced scientists to make major changes in the direction of their research careers, to acquire new research capabilities, to broaden their scientific background, to enlarge their command of an allied research field, or to take time from regular professional responsibilities to increase their capabilities for engaging in health-related research. (Applicants should use the F33 guidelines and Form PHS 416-1 to apply for support.)

(3) *NIH National Research Service Award Individual Postdoctoral Fellowship (F32) Guidelines*

These fellowships are awarded to qualified individuals holding the doctoral or equivalent degree to support full-time research training in designated biomedical science areas. (Applicants should use the F32 guidelines and PHS 416-1 to apply for support.)

(4) *NIH National Research Service Award Short-Term Training for Students in Health Professional Schools (T35) Guidelines*

The goal of these institutional training awards is to provide predoctoral students in health professional schools with research experience during off-quarters or summer periods, so as to encourage them into a research career. (Applicants should use the T35 guidelines and the PHS 398 application.)

(5) *Guidelines for Establishing and Operating Consortium Grants*

(Self-explanatory)

(6) *Research Grants to Foreign Institutions and International Organizations*

(Self-explanatory)

(7) *The K Awards-Research Career Program Awards*

Among NIH components, several types of career awards are available to research and academic institutions on behalf of scientists with clear research potential, but requiring additional experience in a productive scientific environment in preparation for careers in independent biomedical research. (Applicants should use the PHS 398.)

(8) *Academic Research Enhancement Award (AREA, R15) Guidelines*

Support is provided to scientists at eligible domestic institutions for small-scale health-related research projects, such as pilot research projects and feasibility studies; development, testing, and refinement of research techniques; and similar discrete research projects that demonstrate research capability. This award is directed toward those smaller public and private colleges and universities which provide undergraduate training for a significant number of the U.S. research scientists. (Applicants should use the PHS 398 with the AREA guidelines.)

Applications Available from Other Offices

Small Business Innovation Research (SBIR) Applications
SBIR Phase I (PHS 6246-1)
SBIR Phase II (PHS 6246-2)
Small Business Technology Transfer, Phase I (PHS 6246-3)
Small Business Technology Transfer, Phase II (PHS 6246-4)

Available from:
PHS SBIR/STTR Solicitation Office
13687 Baltimore Avenue
Laurel, MD 20707-5096
Phone: (301) 206-9385
Fax: (301) 206-9722
E-mail: a2y@cu.nih.gov
Web site: http://www.nih.gov/grants/funding/sbir.htm

International Research Fellowship Award Application (NIH 1541-1)
Available from:
Fogarty International Center
(301) 496-1653

Nonresearch Training Grant Application (PHS 6025)
Available from:
Health Resources and Services Administration
(301) 443-6960

Health Services Project Application (5161-1)
Available from:
Substance Abuse and Mental Health Services Administration (SAMHSA)
(301) 436-8451

If You Want to Obtain.....

- an application kit or forms, contact the local office of sponsored research.
- publications about NIH extramural research and research training programs, visit the Grants pages of the NIH Web site system: http://www.nih.gov/grants/oer.htm.

If You Want to Know More About....

- The telephone number for an NIH staff person, visit the NIH Web site: http://directory.nih.gov. Telephone: (301) 496-4000 (the NIH locator).
- NIH Extramural Research and Research Training Programs (general information), visit the Grants pages of the NIH Web site: http://www.nih.gov/grants/oer.htm. E-mail: GrantsInfo@nih.gov. Telephone: (301) 435-0714.
- A specific application, before review, telephone or e-mail the Scientific Review Administrator named on the “snap-out-mailer”.
- Receipt and referral of an application, contact: Division of Receipt and Referral Center for Scientific Review Telephone: (301) 435-0715.
- Human Subject Protections, Institutional Review Boards, or related assurances (Office for Protection from Research Risks), visit the Office of Protection from Research Risks Web site: http://www.nih.gov/grants/oprr/oprr.htm. Telephone: (301) 496-7041.
- Animal Welfare and related regulations and assurances (Office for Protection from Research Risks (OPRR)). Visit the OPRR Web site: http://www.nih.gov/grants/oprr/oprr/oprr.htm. Telephone: (301) 496-7163.

Research Career Award

Form Approved Through 2/28/01
OMB No. 0925-0001

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Additional Instructions for Preparing Individual Research Career Award (RCA) Applications — "K" Series

A. Introduction

This section includes additional instructions to be used when applying for an individual Research Career Award (RCA), and includes a summary of current RCA award mechanisms, a substitute Table of Contents (Form LL), and guidelines for reference reports. The instructions in this section of the PHS 398 application should be used along with the instructions in the preceding sections.

These instructions do not cover applications for program awards (K12 and K30), which provide support for all institutional career development programs. Institutions planning such applications should contact the potential awarding component concerning eligibility, award criteria, and application procedures.

Before applying for an RCA, applicants should carefully review general guidelines for the specific career award(s) of interest, noting especially the eligibility requirements, award provisions, requirements for a sponsor, and review criteria. The guidelines are issued periodically in the *NIH Guide for Grants and Contracts* and should be available from the sponsored programs office of the applicant institution. General NIH program announcements are available on the NIH Web site (http://www.nih.gov/grants/) and may be requested from GrantsInfo, National Institutes of Health (NIH), e-mail: GrantsInfo@nih.gov, (301) 435-0714.

In addition, the eligibility criteria, support levels, and other important aspects of specific career awards, including availability, may depend on which NIH Institute or Center supports the award. For this reason, **it is strongly recommended that applicants contact the program director of the appropriate awarding component prior to the preparation of an application.** A list of program contacts is available in the general NIH program announcements for these programs (see http://www.nih.gov/grants/).

B. Summary of Individual Career Awards

Award Type	Sponsor/(Mentor)	Reference Letters
K01 Mentored Research Scientist Development Award	Yes	Yes
K02 Independent Scientist Award	No	No
K05 Senior Scientist Award	No	No
K07 Academic Career Award	*	*
K08 Mentored Clinical Scientist Development Award	Yes	Yes
K22 Career Transition Award	*	Yes
K23 Mentored-Patient Oriented Research Career Development Award	Yes	Yes
K24 Mid-Career Investigator Inpatient Oriented Award	No	No

**Varies with career status and source of award. Check the announcement.*

C. SECTION 1: Basic Administrative Data

1. Face Page (AA)

Item 2. Response to Specific Program Announcement. Check "Yes." Provide appropriate K Award Type Number (see previous section) and title for the specific type of RCA requested.

Item 3. Principal Investigator/Program Director. Provide the name of the candidate. Indicate the doctoral degree(s) in 3b. If the candidate is not located at the applicant organization at the time the application is submitted, the mailing address (Item 3e) and telephone (Item 3h) should indicate where the applicant can be reached prior to the requested award date; items 3d, 3f, and 3g should reflect the candidate's projected position at the applicant organization.

Item 6. Dates of Proposed Period of Support. The period of support must be within specified limits for the type of RCA requested. If the application involves a change of applicant organization for an active RCA awardee, indicate the time remaining in the original award.

2. Description and Personnel (Form Page 2-BB)

Description. Provide an abstract of the whole application (candidate, environment, and research). Include the candidate's immediate and long-term career goals, research career development plan, and a description of the research project.

Personnel. Name the candidate and, if applicable, the sponsor(s) (mentor). For RCAs with no sponsor, name the candidate's department head and senior staff member, if other than the department head, who will assume responsibility for the candidate's research career development at the applicant organization.

3. Table of Contents (Substitute Form Page 3-LL)

Use the substitute Table of Contents at the back of this section. Follow the instructions below for verifying citizenship.

Citizenship. All applicants must provide information regarding citizenship on the bottom of the substitute Table of Contents. Candidates for an award must be citizens or noncitizen nationals of the United States or its possessions and territories, or must have been lawfully admitted to the United States for permanent residence by the time of the award.

4. Budget Information

a. Detailed Budget for Initial Budget Period (Form Page 4-DD). Do not complete the Form Page 4-DD. It is not required nor will it be accepted at the time of application. In some cases it may be requested prior to award. Should Form Page 4-DD be requested prior to award, the following instructions regarding Personnel will apply:

Personnel. Base the candidate's request on a full-time, 12-month appointment, following the salary and fringe benefits limits specified in the program announcement and individual Institute guidelines for the specific RCA program. If part of the research funds requested will be for supporting personnel, e.g., research assistants, they should be listed here. However, the entire salary, including fringe benefits and other items, cannot exceed the limits of the specific RCA program.

b. Budget for Entire Proposed Period of Support (Form Page 5-EE). Do not complete the categorical budget table on Form Page 5-EE. Only the requested total direct costs for each year and total direct costs for the entire proposed period of support should be shown. Begin the budget justification in the space provided, using continuation pages as needed.

Budget Justification
List the name, role on project, and percent effort for all project personnel (salaried or unsalaried) and provide a narrative justification for each person based on his/her role on the project and proposed level of effort.

Identify all consultants by name and organizational affiliation and describe the services to be performed.

Provide a narrative justification for any major budget items, other than personnel, that are requested for the conduct of the project that would be considered unusual for the scope of research. No specific costs for items or categories should be shown.

5. Biographical Sketch (Form Page 6-FF)

A biographical sketch is required for the candidate, sponsor(s), co-sponsor(s), and other key personnel. Biographical sketches should follow in the order as listed on Form Page 2-BB. Sponsor(s), co-sponsor(s), and other key personnel should follow the instructions on Form Page 6. Candidates should follow the instructions below.

Education. The candidate should give the month as well as the year for each degree conferred. For nondegree education, indicate the time period covered. List professional certifications received within the last 10 years.

Research and/or Professional Experience. The candidate should use the headings given below instead of the instructions on the biographical sketch. Identify each heading. **Do not use more than two pages.**

Employment
Start with the first position held following the baccalaureate and give a consecutive record to date. Indicate the department and organization, department head or supervisor, rank, tenured or nontenured, status (full-or part-time), and inclusive dates. Where applicable, include information on military service, internships, residencies, research assistantships, fellowships, etc.

Honors
List academic and professional honors.

Professional Societies
Identify professional societies and related organizations in which membership has been held within the last 10 years, giving dates.

Publications
List all publications (chronologically), divided into the following groups:

- Original research and theoretical treatises;
- Nonexperimental articles, e.g., review of literature in field, etc.;
- Books, pamphlets, etc.

If the list of publications cannot be accommodated within the two page limit, select the most pertinent publications. If a copy of a publication is being submitted with the application, indicate with an asterisk and footnote ("copies sent"). For competing continuation applications, also identify with a double asterisk and appropriate footnote all papers published during the concluding period of support.

6. Other Support (Format Page 7-GG)

For the Mentored Career Awards: Mentored Research Scientist Development Award (K01), Mentored Clinical Scientist Development Award (K08), Developmental Academic Award (K07), and the Mentored Patient Oriented Research Career Development Award (K23), modified other support pages should be submitted for the sponsor(s) and co-sponsor(s), **not the candidate**. Information on the sponsor's and co-sponsor's current and pending research support **relevant to the candidate's research plan** should be included. Overlap and level of effort information **is not** required at the time of application.

For all other RCAs, Other Support pages **should not** be submitted at the time of application.

Information on all active support for the candidate, sponsor(s), co-sponsor(s), and key personnel may be requested prior to award.

7. Resources (Form Page 8-HH)

Carefully complete this section following instructions on the form. The information provided is of major importance in establishing the feasibility of the project to further the applicant's research career.

D. SECTION II: Specialized Information

1. Introduction to Revised Application.

This applies only to amended/revised applications. **Not to exceed three pages.**

List each area of concern noted in the summary statement for the previous application and provide a detailed response to each concern. Summarize clearly the changes that have been made in the revised application. Do not include an extensive description of each change in this introduction.

Highlight paragraphs with significant changes since the previous application by appropriate bracketing, indenting, or changing of typography, unless the changes are so extensive as to include most of the text. This exception should be explained in the text. Do not underline or shade changes.

2. Letters of Reference

Letters are required for all new and revised RCA applications, except for the K02, K05, K24 and for experienced investigators submitting a K07. See specific program guidelines for more information. **Applications with fewer than three reference letters will be returned without review.**

Complete the upper section of the Reference Guidelines (Form MM), including the application submission deadline. Then send copies of Form MM to those who have agreed to serve as referees. Referees should be provided with postage-paid return envelopes *addressed to the candidate* with the following words in the front bottom left corner — "DO NOT OPEN — PHS USE ONLY." **Attach unopened references to the Face Page of the original application and submit the entire package by the submission deadline.** Applicants reapplying must also include reference letters.

Such letters are critically important and should address the candidate's competence and potential to develop into an independent biomedical or behavioral investigator. Only those individuals who can make the most meaningful comments about the candidate's professional training and qualifications for a research career should be used. **The sponsor/mentor of this application cannot be counted as a referee.**

Where possible, select some referees (knowledgeable about your qualifications) who are not from your current department or organization. Request reference letters only from individuals who will be able to return them in time for submission of the application. Consider any factor (e.g., illness or extended vacation) that might cause an inordinate delay.

3. The Candidate

a. Candidate's Background

Use this section to provide any additional information not described in the biographical sketch *(Form Page 6)*, such as research and/or clinical training experience.

b. Career Goals and Objectives: Scientific Biography

Describe your past scientific history, indicating how the award would fit into past and future research career development. If there are consistent themes or issues which have guided previous work, these should be made clear; if your work has changed direction, the reasons for the change should be indicated. It is important to justify the award and how it would enable you to develop or expand your research career.

c. Career Development/Training Activities During Award Period

Stress the new, enhanced research skills you will acquire as a result of the proposed award. If you have considerable research experience in the same areas as the proposed research, reviewers may determine that the application lacks potential to enhance your research career. For mentored awards, describe structured activities, such as course work or technique workshops, which are part of the developmental plan.

Briefly discuss each of the activities, except research, in which you expect to participate. Include a percentage of time involvement for each activity by year and explain how the activity is interrelated with the proposed research and the career development plan.

4. Statements by Sponsor(s), Consultant(s), and Collaborator(s)

For mentored awards (see Summary of Awards table, Section B), the sponsor must explain how the award will enhance the development of the candidate's research career. The program, as proposed by the sponsor and candidate, must provide, in detail, the plan for the candidate's training and research career development as well as a clear commitment of staff time, facilities, and resources by the sponsor. This description must include not only research, but also other developmental activities, such as seminars, scientific meetings, training in the responsible conduct of research, and presentations. It should discuss expectations for publications over the entire period of the proposed project. The sponsor should describe the candidate's teaching load for the period of the award (number and

types of courses or seminars), clinical responsibilities (including number of patients currently seen and professional consultations), committee and administrative assignments, and proportion of time available for research. The sponsor and the sponsoring institution must provide assurances that the candidate will be released for the amount of time required by the RCA.

List all cosponsors, consultants, and collaborators involved with this project. **Letters** from each cosponsor, consultant, and collaborator, confirming their participation in the project and describing their specific roles, **must be included in this section of the application. Do not place these letters in the Appendix.**

5. Environment and Institutional Commitment to Candidate

a. Description of Institutional Environment

The sponsoring institution must document a strong, well-established research program related to the candidate's area of interest, including the names of key faculty members relevant to the candidate's proposed developmental plan. Referring to the resources description (Form Page 8-HH), indicate how the necessary facilities and other resources will be made available for career enhancement as well as the research proposed in this application. Describe opportunities for intellectual interactions with other investigators, including courses offered, journal clubs, seminars, and presentations.

b. Institutional Commitment to Candidate's Research Career Development

Introduction
The institutional commitment should document the agreement of the institution to provide adequate time and support for the candidate to devote nearly full-time to research career development for the entire period of the proposed award. The institution should provide the equipment, facilities, and resources necessary for a structured career development. It is essential to document the institution's commitment to the retention, development, and advancement of the candidate during the period of the award.

Because of the diverse types of K awards, applicants should contact an appropriate program director at NIH to determine the level of commitment required for a specific application.

Agreement
The applicant organization must:

(1) Agree to release the candidate from other duties and activities to devote the required percentage of time for development of a research career. Describe actions that will be taken to ensure this, for example, the candidate's teaching load, committee and administrative assignments, and clinical or other professional activities for the current academic year. Include the proportion of time currently available for the candidate's research experience and what the candidate's institutional responsibilities will be in the event that an award is made. Also describe the candidate's academic appointment, bearing in mind that it must be full-time, and that the appointment (including all rights and privileges pertaining to full faculty status) and the continuation of salary are not contingent upon the receipt of this award. For most K awards, commitment of 75-80 percent of time is required;

(2) Provide the candidate with appropriate office and laboratory space, equipment, and other resources and facilities (including access to clinical and/or other research populations) to carry out the proposed research plan; and

(3) Provide appropriate time and support for any proposed sponsor(s) and/or other staff consistent with the career development plan.

Signatures
The institutional commitment must be dated and bear the signature of the head of the organizational unit who is authorized to commit the institution to the agreements and assurances listed above. In most cases, this will be the dean or the chairman of the department. "Per" signatures are not acceptable.

The signature must appear over the signer's name and title at the end of the statement. When a candidate will be working away from the home institution, signatures from both the home and the host institution are required.

The sponsoring institution, through its signatures on the application and the institutional commitment, certifies that all items outlined above will be provided and that the institution will abide by the applicable assurances and PHS policies.

6. Research Plan

The Research Plan is the major component of the research career development plan. It is important to relate the research to the candidate's goals and aspirations. The candidate should describe how the research, coupled with other developmental activities, will provide experience to launch and conduct an independent career.

Applicants for all types of individual K awards should provide a Research Plan to be carried out in the course of this award. For most types of research, the plan should include: a specific hypothesis; a list of the specific aims and objectives that will be used to examine the hypothesis; a description of the methods/approaches/techniques to be used in each aim; a discussion of possible problems and how they will be avoided; and, when appropriate, alternative approaches that might be tried if the initial approaches do not work.

The plan should be appropriate to develop skills needed by a researcher. Projects that lack a clearly stated aim or hypothesis, such as studies involving routine data gathering to see where leads might develop and other types of descriptive projects, usually do not receive favorable recommendations from reviewers. This also applies to projects that are overly ambitious and describe more work than can be done in the requested time, as well as more routine projects that might be done, in large part, by a skilled technician.

Although candidates are expected to write the Research Plan for mentored K awards, the sponsor should review a draft of the plan and discuss it in detail with the candidate. Review by other knowledgeable colleagues is also helpful.

If the research involves collaboration with individuals, other than the sponsor, who will provide research materials, data, guidance, or advice, then include letters from such individuals documenting their willingness to participate in the project (see page IV-5).

The headings for the first four sections of the **Research Plan** are:

a. **Statement of Hypothesis and Specific Aims,**

b. **Background, Significance, and Rationale,**

c. **Preliminary Studies and Any Results,** and

d. **Research Design and Methods.**

For more information about these sections, see the equivalent headings in the main instructions beginning on page 15.

Note: The total number of pages for Item 3 (The Candidate) and a-d of Item 6 (Research Plan) combined may not exceed 25. In many cases, RCA applications will be shorter than the limit.

Although it is understood that RCA applications do not require the extensive detail usually incorporated in regular research applications, a fundamentally sound research plan and a reasonably detailed methods section should be provided.

In general, less detail will be expected in descriptions of research planned for the future years of the proposed RCA, but there should be sufficient detail to enable the reviewers to determine that the plans for those years, including the methods to be used, are worthwhile and likely to enhance development of the candidate.

Include required information on Gender and Minority Inclusion, Inclusion of Children, Human Subjects, Vertebrate Animals, Consortium/Contractual Arrangements, and Consultants, when applicable. Literature cited should be included in this section. See pages 16-19 for instructions on these items.

7. Appendix

No more than six publications and manuscripts accepted for publication should be submitted with new applications. Do not submit abstracts or unpublished theses.

Note: Do not submit the **Checklist** Page with the application. A completed Checklist will be required prior to award. Facilities and Administration (F&A) costs will be awarded at 8 percent of modified total direct costs.

Institutional National Research Service Award

Form Approved Through 2/28/01
OMB No. 0925-0001

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Additional Instructions for Preparing Institutional National Research Service Award Applications

A. Introduction

This section includes: additional instructions to be used when applying for a competing (new, competing continuation, and supplemental) PHS Institutional National Research Service Award (NRSA); substitute form pages for the table of contents and both budget pages; and instructions for the Research Training Program Plan. Begin by reading the general instructions (on pages 5-6) and then follow both sets of instructions using the Guide for Preparing an Institutional NRSA Application, provided on page V-8.

Prior to preparing an application, consult with the appropriate PHS awarding component. Also review the NRSA Information Statement, noting especially the eligibility requirements, award provisions, payback provisions, and review criteria. The statement can be obtained from GrantsInfo, National Institutes of Health (NIH), (301) 435-0714, e-mail: GrantsInfo@nih.gov. Program announcements, which are issued periodically in the *NIH Guide for Grants and Contracts*, are available from the appropriate PHS awarding component, from grantee offices of sponsored programs or equivalent offices, or from the NIH grants Web site. **The training grant director must explain the terms of the payback service requirement to all prospective postdoctoral training candidates.** A complete description of the service payback obligation is available in the NRSA Information Statement.

B. Specific Instructions

1. Face Page (AA)

Item 2. Response to Specific Request for Application (RFA) or Program Announcement (PA). Indicate "Institutional National Research Service Award" and include the specific PHS awarding component and specialized program area, if applicable.

Item 4. Human Subjects. If the applicant organization has an approved Assurance of Compliance on file with the Office for Protection from Research Risks (OPRR) but, at the time of application, plans for the involvement of human subjects are so indefinite that Institutional Review Board (IRB) review and approval are not feasible, check "'Yes" and insert "Indefinite" at Item 4a. If an award is made, human subjects may **not** be involved until a certification of the date of IRB approval or a designation of exemption has been submitted to the PHS awarding component.

In many instances, trainees supported by institutional training grants will be participating in research supported by research project grants for which the IRB review of human subjects is already complete or an exemption is already designated. This review or exemption designation is sufficient, provided the IRB determines that the research would not be substantially modified by the participation of a trainee. The appropriate grants must be identified along with their IRB review dates or exemption designation. If space is insufficient in Item 4, indicate at 4a "Sec. f," and provide the information under the Research Training Program Plan.

Item 5. Vertebrate Animals. If the applicant organization has an approved Animal Welfare Assurance on file with the Office for Protection from Research Risks (OPRR) but, at the time of application, plans for the involvement of vertebrate animals are so indefinite that Institutional Animal Care and Use Committee (IACUC) review and approval are not feasible, check "Yes" and insert "Indefinite" at Item 5a. If an award is made, vertebrate animals may not be involved until a verification of the date of IACUC approval has been submitted to the PHS awarding component.

In many instances, trainees supported by institutional training grants will be participating in research supported by research project grants for which the IACUC review is already complete. This review is sufficient, provided the IACUC determines that the research would not be substantially modified by the participation of a trainee. The appropriate grants must be identified along with their IACUC review dates. If space is insufficient in Item 5, indicate at 5a "Sec. g," and provide the information under the Research Training Program Plan.

Item 6. Dates of Entire Proposed Period of Support. The usual starting date for an institutional NRSA is July 1, but there are other possible starting dates. Consult the review and award schedule on page 21 in the general instructions. A few PHS awarding components restrict receipt and review dates to once a year. **Applicants are strongly encouraged to contact appropriate awarding component staff before submitting an application.**

2. Description, Performance Sites, and Key Personnel (Form Page 2-BB)

Description. Summarize the essence and major features of the program. Include research areas and disciplines, levels of training, numbers and background experience of trainees, anticipated duration of training, and primary facilities.

3. Table of Contents (Form Page 3-NN)

Use the substitute Table of Contents page (NN) in this addendum.

4. Detailed Budget for Initial Budget Period (Form Page 4-OO)

Use the substitute pages (OO and PP) in this addendum and follow the instructions below.

Refer to the NRSA Information Statement or consult the PHS awarding component for current allowable costs and stipend levels. Provide information where possible on the substitute Form Page OO, with additional details starting in the budget justification block on substitute Form Page PP.

Stipends

Enter the number of trainees and total stipend amount for each trainee category as appropriate. If a category contains different stipend levels, e.g., for varying levels of postdoctoral experience and/or varying appointment periods, itemize. Enter the total stipends for all categories.

Tuition, Fees, and Self-only Health Insurance

Explain in detail the composition of this item. Itemize tuition, individual fees, and medical insurance. If tuition varies, e.g., in-state, out-of-state, student status, identify these separately. Tuition at the postdoctoral level is limited to that required for specified courses. Tuition and fees (including self-only health insurance) may be requested only to the extent that the same resident or nonresident tuition and fees are charged to regular non-Federally supported students.

Trainee Travel

State the purpose of any travel, giving the number of trips involved, the destinations, and the number of individuals for whom funds are requested, bearing in mind that PHS policy requires less than first-class air travel be used. Justify foreign travel in detail, describing its importance to the training experience.

Training Related Expenses

Funds to defray other costs of training, such as staff salaries, consultant costs, equipment, research supplies, staff travel, etc., are requested as a lump sum based on the predetermined amount, specified in the program announcement, per predoctoral and postdoctoral trainee. Give the number of trainees at each predetermined rate and enter the total dollar figure. No further itemization or explanation is required.

5. Budget for Entire Proposed Period of Support (Form Page 5-PP)

Use the substitute page (PP) in this addendum.

6. Biographical Sketch (Form Page 6-FF)

Include biographical sketches, not to exceed two pages each, for all professional personnel contributing to the training program. Assemble sketches with the program director first and others following in alphabetical order.

7. Other Support (Format Page 7-GG)

Not applicable.

8. Resources (Form Page 8-HH)

Describe the facilities and resources that will be used in the proposed training program. Indicate in what ways the applicant organization will support the program, e.g., supplementation of stipends.

9. Research Training Program Plan

The following instructions are for new and competing applications. If you are preparing a **revised** or **supplemental** application, first see page 14. Then follow the outline suggested below in describing the Research Training Program Plan. **Do not exceed 25 pages of narrative for sections a-d.** Much of the information requested may be provided in tabular form, which will not be counted toward the page limitation; however, these table pages should be numbered consecutively to maintain the integrity of the application. If tables are placed in the Appendix, they should be numbered consecutively.

Before completing the Training Plan, contact the appropriate PHS awarding component, which may have further advice or suggestions for organizing the relevant data into particular formats.

a. Background

Give the rationale for the proposed research training program, relevant background history, and the need for the research training proposed. Indicate how the proposed program relates to current training activities.

Summarize the research training activities of the major participating unit(s) and department(s) represented in the proposed program. Give the current number of faculty members in each unit and department, as well as the total numbers of current predoctoral students and postdoctoral trainees.

In a table, list all current and pending training support available to the participating faculty and department(s). Include funding source, complete identifying number, title of the training program, name of the program director, project period, number of training positions (predoctoral and postdoctoral), and amount of the award. For each grant listed, name only those participating faculty members who are also named in this application and indicate their percent effort in those programs.

b. Program Plan

(1) Program Direction

Describe the program director's relevant scientific background, research, experience in research training, and qualifications for providing leadership for the program. Indicate the program director's percent of effort in the proposed program.

Describe the administrative structure of the program and the distribution of responsibilities within it, including the means by which the program director will obtain continuing advice with respect to the operation of the program.

(2) Program Faculty

List each training faculty member, his/her primary departmental affiliation, role, and percent of effort in the proposed program.

Describe each faculty member's research that is relevant to this program and indicate how trainees will participate in this research. Current and future research training opportunities should be indicated by providing a **table** that lists, for each participating faculty member, active and pending **research** support. Include all Federal, non-Federal, and institutional research grant and contract support. If none, state "None". Include the source of support, grant number and title, dates of the entire project period, and annual direct costs. If part of a larger project,

identify the principal investigator and provide the above data for both the parent grant and the subproject.

Describe the extent to which participating faculty members cooperated, interacted, and collaborated in the past, including joint publications and joint sponsorship of student research.

In a table, for each faculty member participating in this application, list all past and current students for whom the faculty member has served, or is serving, as thesis advisor or sponsor (limit to past 10 years). For each student listed, indicate: (1) the training level, either predoctoral or postdoctoral; (2) the training period; (3) the institution and degree received prior to entry into training, including date; (4) title of the research project; and (5) for past students, their current positions, and for current students, their source of support. **In competing continuation** applications, mark those trainees who were or are supported by this training grant with an asterisk. Individuals who were trained by proposed participating faculty members at sites other than the applicant organization may be included but should be specifically identified. For **new** applications, list representative recent publications of some of the above students. For **competing continuation** applications, publications of past trainees supported by this grant, provided in the Progress Report of this application, will suffice.

(3) Proposed Training

Describe the proposed training program. Give the level and number of trainees. For postdoctoral trainees, provide the proposed distribution by degree (M.D., Ph.D., etc.). Describe course work and research opportunities, the extent to which trainees will participate directly in research, and the duration of training, i.e., usual period of time required to complete the training offered.

Indicate how the individual disciplinary and/or departmental components in the program are integrated and coordinated for the program and for an individual trainee's experience.

For training programs emphasizing research training for clinicians, describe the interactions with basic science departments and scientists. In addition, include plans for ensuring that the training of these individuals will provide a substantive foundation for a competitive research career. Generally, a minimum of 2 years of research training is required for all postdoctoral trainees with health professional degrees. Describe fully any trainee access to and responsibility for patients including percent of effort.

Provide representative examples of programs for individual trainees. Include curricula, degree requirements, didactic courses, laboratory experiences, qualifying examinations, and other training activities, such as seminars, journal clubs, etc. Describe how the preceptor and research problems are chosen, how each trainee's program will be guided, and how the trainee's performance will be monitored and evaluated.

(4) Trainee Candidates

Describe recruitment plans, including the sources and availability of trainees. Give the qualifications of prospective trainees and the criteria and procedures by which trainees will be selected.

The size of the applicant and trainee pool and their training progress should be presented **in a table**. For each participating department/unit for each of the past 5 years, give: (1) the number of individuals who have formally applied for training; (2) the number offered admission; (3) the number who entered training; (4) the number who completed or are currently in training; and (5) the number who left the program. Indicate whether

these individuals were applying for predoctoral or postdoctoral training, and for postdoctoral fellows, give their degrees (M.D., Ph.D., etc.).

The qualifications of prospective **predoctoral** trainees and the selectivity of the program should be presented **in a table** which anonymously indicates the credentials and application outcomes of the predoctoral applicant pool for the most recent year for each participating department and unit. For each applicant (identified with a number in sequence, rather than by name, to safeguard privacy), give: the previous institution attended, Graduate Record Examination scores, and grade point average. Indicate whether applicants were or were not offered admission, which applicants matriculated, and whether applicants were U.S. citizens or had permanent resident status.

The qualifications of prospective **postdoctoral** trainees in the most recent applicant pool should be presented **in a table** which indicates their: name, degrees and year awarded, previous institution, thesis research topic and preceptor, and residency training when appropriate. Indicate whether applicants were or were not offered admission, which applicants entered the program, and whether applicants were U.S. citizens or had permanent resident status.

c. Recruitment of Individuals from Underrepresented Racial/Ethnic Groups

The policy of the NIH is to promote broad and systematic efforts to recruit individuals from minority groups currently underrepresented in biomedical and behavioral research. NRSA programs are intended to attract and train individuals to pursue independent careers as investigators. Accomplishments of NRSA programs in these areas, with respect to recruiting and retaining individuals from underrepresented groups, will ensure that minority scientists are progressively better represented in the National research effort.

The application must contain information related to the program's plan and experiences in recruiting and training graduate students and/or postdoctoral trainees from racial or ethnic groups, including Blacks, Hispanics, Native Americans, Alaskan Natives, and Pacific Islanders. These groups have been found to be underrepresented in biomedical or behavioral sciences nationally. **Applications without a description of minority recruitment efforts will be considered incomplete and may be returned to the applicant.** The description of such plans and efforts should be arranged as follows:

History
In new applications, describe efforts to recruit minority students into the existing training program. In competing continuation applications, describe past efforts to recruit and retain underrepresented minority students into NRSA training positions.

Achievements
Provide recruitment statistics indicating the number of minority individuals who applied to the program and/or participating units in each of the past 3 years. Give the number of minority candidates offered admission and the number who entered the program. For those who entered the program, indicate their current status, e.g., training, graduated or completed training, and how they were supported. For those who have left the program or completed training, include information about their subsequent career development or employment. In competing continuation applications, indicate which of the minority individuals were supported by the NRSA grant.

Proposed Plans
Describe steps to be taken during the proposed award period regarding the identification, recruitment, and retention of graduate students and postdoctorates from underrepresented groups. Consider the success and/or failures of recruitment strategies used in the past. In particular, describe the specific efforts to be undertaken by the training program and how these might relate to the recruitment efforts of the medical school, graduate school,

and/or the university at large. In most cases, institutional efforts alone will not satisfy the requirement to recruit individuals from underrepresented groups.

d. Plan for Instruction in the Responsible Conduct of Research

Every NRSA trainee must receive instruction in the responsible conduct of research, and each training grant application **must** include a description of the plan to provide trainees with formal and informal instruction on scientific integrity and ethical principles in research. Institutions are encouraged to incorporate this instruction into the training of other non-NRSA supported pre- and postdoctoral trainees.

Review of applications lacking a plan for instruction in the responsible conduct of research may be delayed until a plan is provided.

There are no specific curriculum or format requirements for this instruction; however, conflict of interest, responsible authorship, policies for handling misconduct, policies regarding the use of human and animal subjects, and data management are areas that are strongly suggested for consideration.

The plan must address the format and subject matter of the instruction and the frequency and degree of participation of the trainees and faculty that are expected. A rationale for the proposed plan of instruction must be provided. For **competing** continuation applications, progress reports on the type of instruction provided, the degree of student participation, and other relevant information will be required.

e. Progress Report (Competing Continuation Applications Only)

Briefly describe the accomplishments of the training program. State the period covered.

Provide **a table** documenting for each year of the current project period, the program's actual assignment of awarded trainee positions. Provide: (1) the total number of positions awarded in each year; (2) the number of predoctoral trainees appointed and months of support committed; and (3) the number of postdoctoral trainees appointed, with what degrees, at what levels, and for how many months. Indicate and explain any trainee positions that were not filled.

Provide **a table** listing all trainees who were, or are, supported by this training grant. (Where applicable, provide the data for the past 10 years.) For each student give: (1) the name; (2) the year of entry into the training program; (3) prior institution, and degree at entry; (4) the source of support during each year of training, e.g., this training grant, another (specify) training grant, research grant, university fellowship, individual (specify) fellowship, etc.; (5) the research mentor; (6) the research topic; and (7) for trainees who have completed the program, their current positions and institutional affiliations. Give a brief summary of the research conducted by each trainee supported during the period covered, and list all publications that resulted from the work done during training. Where possible for past trainees, describe the extent of their current involvement in research, including research grant support and representative recent publications. This information will be used to track the pattern of support of trainees and the subsequent research career development of former trainees.

If any postdoctoral trainee with a health professional degree who was appointed to the grant during the most recent award period received less than 2 years of research training, explain why. This explanation should appear in the narrative section of the Progress Report.

Describe any specific effects of this training program on curriculum and/or research directions.

Describe how the funds provided under Training Related Expenses were utilized to benefit the program.

f. Human Subjects

As indicated earlier in these instructions for Item 4 on the Face Page, where appropriate include a list of already reviewed research project grants and their IRB review dates or exemption designations.

g. Vertebrate Animals

As indicated earlier in these instructions for Item 5 on the Face Page, where appropriate include a list of already reviewed research project grants and their IACUC review dates.

10. Appendix

Appendix material is generally not needed with training grant applications. Oversized documents, brochures, and catalogues may be exceptions. If tables or other materials are included, the pages should be numbered consecutively. Five collated sets should be submitted.

11. Checklist (II)

Inventions and Patents. Not applicable.

Facilities and Administration (Indirect) Costs. Facilities and Administration (F&A) costs under institutional NRSAs, other than those issued to State or local government agencies, will be awarded at 8 percent of total allowable direct costs (exclusive of tuition and related fees). Equipment is also excluded from the F&A costs on those training grants, where Training Related Expenses are not calculated on a lump-sum basis, such as the MARC Honors Undergraduate Research Training Program. State and local government agencies will receive awards at their full F&A cost rate.

12. Personnel Report (JJ)

Not applicable.

SEQUENTIAL GUIDE FOR PREPARING AN INSTITUTIONAL NRSA APPLICATION

(Requires use of both the General and NRSA Additional Instructions.)